EXHIBIT H

1	IN THE UNITED STATES DISTRICT COURT
2	FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3	CHARLESTON DIVISION
4	
5	IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS
5	LIABILITY LITIGATION
7	
8	MASTER FILE NO. 2:12-MD-02327
9	MDL NO. 2327
)	
-	GENERAL CAUSATION RE: PROLIFT and PROLIFT+M
2	
,	
4	
5	PURSUANT TO NOTICE, the deposition of BRIAN
5	FLYNN, M.D. was taken on behalf of the Plaintiff at
	Denver Marriott West, 1717 Denver West Boulevard,
	Golden, Colorado, on April 14, 2016, at 11:52 a.m.,
	before Melanie L. Giamarco, Registered Merit Reporter,
)	Certified Realtime Reporter, and Notary Public within
L	Colorado.
3	
4	GOLKOW TECHNOLOGIES
	877.370.3377 ph/ 917.591.5672 fax
5	deps@golkow.com

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3	For the Plaintiffs:	3	NUMBER DESCRIPTION Exhibit 7 AUA Update Series 2010 titled:	135
	GREG BENTLEY, ESQ. SHEA SHAVER, ESQ	4	The Use of Surgical Mesh for Incontinence and Prolapse Surgery:	
4	ZONIES LAW, LLC	1	Indications for Use, Technical	
	1900 Wazee Street	5	Considerations and Management of	
5	Suite 203	6	Complications ETH.MESH.00270760 -	
	Denver, Colorado 80202	7	ETH.MESH02270771	
6		′	Exhibit 8 Study by Dr. Velemir, et al.,	158
8	For the Defendants Johnson & Johnson and Ethicon:	8	titled: Transvaginal mesh repair	
°	BARRY J. KOOPMANN, ESQ. DAVID J. DUKE, ESQ.	9	of i=anterior and posterior vaginal wall prolapse: a clinical	
9	BOWMAN AND BROOKE, LLP		and ultrasonographic study	
	150 South Fifth Street	10	ETH.MESH.01192895 - ETH.MESH.01192901	
10	Suite 3000	11		1.60
	Minneapolis, Minnesota 55402	12	Exhibit 9 E-mail string ending 12/19/11 from Dr. Flynn to Dr.	168
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3 4	INDEX EXAMINATION OF BRIAN FLYNN, M.D. March 24, 2016 By Mr. Bentley By Mr. Koopmann 4, 217, 229 By Mr. Koopmann 180, 228	2 3 4	BRIAN FLYNN, M.D., after having been duly sworn, was examined and testified as follows:	
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drives for this deposition? A. I don't have any additional flash drives. I do have an additional CD and a few other invoices that are specific to this deposition. Q. Okay. And you also brought some binders with what appears to be — or could you tell me what are in the binders? A. I have three binders, one is for Prolift, and the other two are for Prolift+M. Q. Okay. And you brought a CD. Do you have an understanding of what's on that CD? A. It's some Prolift and — Prolift studies and pelvic organ prolapse studies. And I have that CD here. Q. Are those studies that are in addition to what was on the flash drives, or just — A. I think it repeats. I believe these studies are also on the flash drive. But just for completeness, in case they were not, I brought the CD. Q. Do you have an understanding of when that CD was made? A. It was sent to me — I received it on July 29th, 2015. Q. And then I have in front of me a preparing your Prolift report; do you agree with that? A. I do. Q. And then on Exhibit 1, you have a telephone conference of 1.25 hours and a four-person, right, in-person conference for for hours, so five and a quarter plus 33, so we have and a quarter hours in total preparation; would agree with that? Do the math. A. I agree with that? Q. Okay. And the last date you have on Exhibit 2 is October 2, 2015. Subsequent to th date, have you done any work on Prolift? A. Very little. Most of the work was done in preparation of this report for a case in the fall, and then before I submitted this this report and a quarter hours in total preparation; would agree with that? Q. Okay. And the last date you have on Exhibit 2 is October 2, 2015. Subsequent to th date, have you done any work on Prolift? A. Very little. Most of the work was done in preparation of this report for a case in the fall, and then before I submitted this this year i 2016, I went through the final draft and signed on February 26, so there was some very minor editing after those dates. Q. Okay. And you just testified that you don't believe y			<i>z</i> ,	
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21 (Exhibit 2 was marked for identification.) 22 Q. (By Mr. Bentley) So on Exhibit 1, you 23 list 21 hours of preparation for the Prolift 24 report, and on Exhibit 2, you list 12 hours. 25 List at this point? 26 A. I've reviewed a number of depositions				
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142 SO YOU SDEIL ADDIOAIHAICIY SS HOUIS 143 ICCCILIY, SO I III HOLCCITAIH II I III HOKIII2 AL		- ·		•
	25	so you spent approximately 33 nours	23	recently, so this not certain if this looking at

		<u>,</u> ,	
	Page 10		Page 12
1	the expert report list here, so there'd be some	1	question. That calls for work-product information.
2	depositions in addition to these reports that I've	2	Q. (By Mr. Bentley) Did you physically
3	looked at.	3	type the words that are in your report that's dated
4	Q. And what depositions have you reviewed?	4	February 26, 2016?
5	A. I've looked at a report from	5	A. I did.
6	Dr. Ostergard, Dr. Blaivas and Dr. Elliot. I've	6	Q. No one else typed any words for you?
7	looked at a number of reports from	7	MR. KOOPMANN: Object to form. Instruct the
8	Doctors Rosenzweig and Margolis, so it's hard for	8	witness not to answer the question.
9	me to know if which reports or which depositions	9	Q. (By Mr. Bentley) Did you copy and paste
10	because they're from multiple cases, but there may	10	any section of this report?
11	be one from Rosenzweig or from Margolis.	11	A. As I mentioned earlier, the Prolift
12	Q. And how did you decide to review those	12	report did carry over into the +M report, so yes,
13	specific depositions?	13	for the Prolift+M report.
14	A. They were sent to me by Ethicon counsel.	14	Q. So aside from the Prolift and the
15	Q. Did you request to review any other	15	Prolift+M report, was any of this content copied
16	depositions?	16	from some other source?
17	A. No, I did not.	17	A. Not that I'm aware of.
18	Q. Have you ever requested to review, say,	18	Q. When you submitted your report, you also
19	internal corporate depositions from Ethicon?	19	submitted a reliance list. Are those materials you
20	A. No, I have not.	20	relied upon in reaching your opinions here?
21	Q. Did these 38 and a quarter hours include	21	A. Yes.
22	any preparation for the Prolift+M at the same time	22	Q. Now, it's fairly extensive. Do you
23	you were doing Prolift?	23	think that you actually reviewed every one of those
24	MR. KOOPMANN: Object to form.	24	materials on that list?
25	A. There's a separate invoice for +M.	25	A. I've at least seen all of them. Some of
	71. There's a separate invoice for 1111.		71. 1 ve at least seen an or drein. Some or
	Page 11		Page 13
1	There's some carryover from the Prolift report to	1	them I've looked at in greater detail than others,
2	the $+M$, so there's a lot less hours on the $+M$, so	2	but these are articles that I rely on or I may rely
3	it would depend on how you want to characterize	3	on in the future.
4	that. But, you know, the +M report took me a lot	4	Q. Had you reviewed some of these articles
5	less time because I had recently completed the	5	prior to writing your report?
6	Prolift report.	6	A. Yes, quite a few of the articles and
7	Q. And have you previously been deposed on	7	quite a few of the PowerPoints and some of the
8	Prolift?	8	media that was created.
9	A. I never have been on either of these	9	Q. But it's your testimony today that
10	products.	10	you've reviewed every one of the documents that's
11	Q. Have you ever been deposed on a product	11	listed on this report, or on this list?
12	that's used to treat prolapse?	12	MR. KOOPMANN: Object to form.
13	A. No, not as an expert. I have as a	13	A. I think this is a comprehensive list. I
14	treating physician.	14	have looked at all of these articles, some greater
15	Q. Now, you submitted your Prolift on	15	than others.
16	February strike that.	16	Q. (By Mr. Bentley) On the section titled
17	You signed your Prolift report on	17	"Production Materials," there's a number of anatomy
18	February 26, 2016; is that correct?	18	videos and instructional videos. Did you watch all
19	A. Yes, that's correct.	19	of those?
20	Q. And did you write that report yourself?	20	A. I can't say for sure if I watched all of
21	A. I did.	21	them. I've watched a number of them. I did
22	Q. Did you receive any assistance in	22	include those on the USB drive, and so there's
23	writing that?	23	quite a bit of media there.
24	MR. KOOPMANN: Object to form.	24	Q. Okay. As we sit here today, is there
25	I'm going to instruct you not to answer that	25	any way for you to tell me which ones you actually
" "	I'm going to mounce you not to answer that	23	any way for you to ten me winen ones you actually

	Page 14		Page 16
1	reviewed and which ones you didn't?	1	the ones that I've used to formulate my opinions.
2	A. Not easily. Not without having to watch	2	Q. So according to that, did you not use
3	all of them, because they're listed by the Ethicon	3	any of the Ethicon production materials to
4	internal number, and so it's not entitled, so I	4	formulate your opinions in this case?
5	can't say just by looking at the reliance list.	5	MR. KOOPMANN: Object to form.
6	Q. And how did you come to receive all of	6	Sorry. Go ahead.
7	these internal Ethicon documents and videos?	7	A. A lot of the Ethicon documents
8	A. They were sent to me either	8	there's quite a bit of overlap with the references,
9	electronically by a zip file or on a CD or on a	9	and so some of the Ethicon documents, especially
10	USB.	10	the PowerPoint presentations, are heavily
11	Q. Did you specifically request any of	11	referenced. So there's some overlap there, but I
12	them?	12	didn't cite that as a unique reference.
			-
13	A. No, I did not.	13	Q. (By Mr. Bentley) Did you formulate your
14	Q. Are there any documents that you would	14	opinions prior to reviewing these Ethicon mesh
15	like to request to see?	15	documents?
16	A. No.	16	A. No, they were given to me, provided to
17	Q. Do you feel that you've been provided	17	me in advance. Some of them I had received over
18	with all the pertinent important documents to reach	18	the fall of 2015, and maybe more recently, but I've
19	your opinions in this case?	19	relied on a number of those in formulating
20	A. Yes.	20	opinions.
21	Q. So in your report, you have footnotes	21	Q. And which ones have you specifically
22	for a number of different studies; is that correct?	22	relied upon to formulate opinions in your report?
23	A. Yes.	23	A. When I looked at some of the PowerPoint
24	Q. But I didn't notice any footnotes that	24	presentations on biomaterials, I think those
25	cite to an Eth mesh or a production document; is	25	PowerPoint presentations have a number of the
	Page 15		Page 17
1	that correct?	1	references, for instance, like the Dietz paper, the
l _		1	references, for instance, fine the Break paper, the
2	A. I would have to read the entire report,	2	admid classification, some of the Moally papers
3	A. I would have to read the entire report, but let me take a look here. I can submit this as	2 3	
	but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five		admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature.
3	but let me take a look here. I can submit this as	3	admid classification, some of the Moally papers that are both referenced in the reliance list and
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3 4 5	but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five references at the end that don't have a number or a	3 4 5	admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature. Q. So is it fair to say you used the
3 4 5 6	but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five references at the end that don't have a number or a first author, so	3 4 5 6	admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature. Q. So is it fair to say you used the Ethicon mesh documents to help direct you to the
3 4 5 6 7	but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five references at the end that don't have a number or a first author, so Q. And what are those five references? A. One is the AUA position statement, the AUGS frequently asked questions, the AUGS position	3 4 5 6 7	admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature. Q. So is it fair to say you used the Ethicon mesh documents to help direct you to the original citations to go to review to formulate
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3 4 5 6 7 8 9	but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five references at the end that don't have a number or a first author, so Q. And what are those five references? A. One is the AUA position statement, the AUGS frequently asked questions, the AUGS position statement, Oxford Levels of Evidence for	3 4 5 6 7 8 9	admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature. Q. So is it fair to say you used the Ethicon mesh documents to help direct you to the original citations to go to review to formulate your opinions in this report? A. It would work in both directions. Many of them I was already familiar with. Some of them
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3 4 5 6 7 8 9 10 11 12 13 14	but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five references at the end that don't have a number or a first author, so Q. And what are those five references? A. One is the AUA position statement, the AUGS frequently asked questions, the AUGS position statement, Oxford Levels of Evidence for practitioners, and then Sunoco MDS. Q. Do you have an understanding that all of those are pubicaly available documents and not internal Ethicon documents? A. Yes, those are all publicly available.	3 4 5 6 7 8 9 10 11 12 13 14	admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature. Q. So is it fair to say you used the Ethicon mesh documents to help direct you to the original citations to go to review to formulate your opinions in this report? A. It would work in both directions. Many of them I was already familiar with. Some of them I was not familiar with and did become aware of those documents after looking at the prof ed material. Q. But none of the Eth mesh documents were important enough to add a footnote citation into
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five references at the end that don't have a number or a first author, so Q. And what are those five references? A. One is the AUA position statement, the AUGS frequently asked questions, the AUGS position statement, Oxford Levels of Evidence for practitioners, and then Sunoco MDS. Q. Do you have an understanding that all of those are pubically available documents and not internal Ethicon documents? A. Yes, those are all publicly available. Q. How did you decide which articles to cite strike that. How did you decide which articles and publicly available documents you cited in your	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature. Q. So is it fair to say you used the Ethicon mesh documents to help direct you to the original citations to go to review to formulate your opinions in this report? A. It would work in both directions. Many of them I was already familiar with. Some of them I was not familiar with and did become aware of those documents after looking at the prof ed material. Q. But none of the Eth mesh documents were important enough to add a footnote citation into your report; is that correct? A. That's not how I would state that. Q. Did you add footnote citations for documents that were important to you?
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five references at the end that don't have a number or a first author, so Q. And what are those five references? A. One is the AUA position statement, the AUGS frequently asked questions, the AUGS position statement, Oxford Levels of Evidence for practitioners, and then Sunoco MDS. Q. Do you have an understanding that all of those are pubically available documents and not internal Ethicon documents? A. Yes, those are all publicly available. Q. How did you decide which articles to cite strike that. How did you decide which articles and publicly available documents you cited in your report how'd you pick which ones to cite to? A. I try to start with articles that I've	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature. Q. So is it fair to say you used the Ethicon mesh documents to help direct you to the original citations to go to review to formulate your opinions in this report? A. It would work in both directions. Many of them I was already familiar with. Some of them I was not familiar with and did become aware of those documents after looking at the prof ed material. Q. But none of the Eth mesh documents were important enough to add a footnote citation into your report; is that correct? A. That's not how I would state that. Q. Did you add footnote citations for documents that were important to you? A. I did. Q. And none of those footnotes include Eth
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	but let me take a look here. I can submit this as an exhibit, but there's one, two, three, four, five references at the end that don't have a number or a first author, so Q. And what are those five references? A. One is the AUA position statement, the AUGS frequently asked questions, the AUGS position statement, Oxford Levels of Evidence for practitioners, and then Sunoco MDS. Q. Do you have an understanding that all of those are pubically available documents and not internal Ethicon documents? A. Yes, those are all publicly available. Q. How did you decide which articles to cite strike that. How did you decide which articles and publicly available documents you cited in your report how'd you pick which ones to cite to? A. I try to start with articles that I've read previously that impact my thoughts and	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	admid classification, some of the Moally papers that are both referenced in the reliance list and also in the Ethicon prof ed literature. Q. So is it fair to say you used the Ethicon mesh documents to help direct you to the original citations to go to review to formulate your opinions in this report? A. It would work in both directions. Many of them I was already familiar with. Some of them I was not familiar with and did become aware of those documents after looking at the prof ed material. Q. But none of the Eth mesh documents were important enough to add a footnote citation into your report; is that correct? A. That's not how I would state that. Q. Did you add footnote citations for documents that were important to you? A. I did. Q. And none of those footnotes include Eth mesh docs; isn't that correct?

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	Page 18		Page 20
1	provide you with all the documents that demonstrate	1	Q. So which Ethicon documents are you
2	Ethicon's knowledge as to complications associated	2	basing your opinions on here?
3	with Prolift?	3	MR. KOOPMANN: Object to form.
4	A. No, I did not.	4	A. As I mentioned earlier, in a number of
5	Q. Would you have liked to have seen	5	the PowerPoint presentations during the prof ed
6	documents strike that.	6	events and things that have been shared with me,
7	If they exist, would you have liked to have	7	there's slides on complication data, and so that
8	seen documents demonstrating Ethicon's internal	8	information was shared when we were preparing for
9	knowledge of complications associated with Prolift?	9	courses and presenting at courses, prof ed courses.
10	A. Some of it was sent to me. I didn't	10	Q. (By Mr. Bentley) So your opinions on
11	have to ask for it. It's in a lot of those	11	this case are based upon complications rates that
12	internal documents, including PowerPoint	12	were provided to you from Ethicon; is that your
13	presentations and information that I received from	13	testimony?
14	prof ed managers, and so I didn't have to	14	MR. KOOPMANN: Object to form.
15	specifically ask for it.	15	A. I received some complication data and
16	Q. So is it your testimony today that you	16	some information. How complete that is, I don't
17	believe you've received and reviewed all internal	17	I can't answer that question.
18	documents demonstrating Ethicon's knowledge of	18	Q. (By Mr. Bentley) And it wasn't
19	complications associated with Prolift?	19	important enough to add a footnote citation into
20	A. I can't say if I've seen all of it. I	20	your report; is that true?
21	don't have any way of knowing what they've sent me.	21	A. I feel that I have, you know, enough
22	But I know they've sent me a number of documents	22	references here, well over a hundred references. I
23	pertaining to complications.	23	feel the document's heavily referenced.
24	Q. And that's information you would have	24	Q. I appreciate that, but that wasn't
25	liked to have reviewed; is that correct?	25	exactly my question, Doctor.
	ince to have reviewed, is that correct:		exactly my question, Doctor.
	Page 19		Page 21
1	MR. KOOPMANN: Object to form.	1	My question was, the Ethicon internal
2	A. Yeah, I appreciated reviewing that	2	documents weren't important enough to add a
3	stuff.	3	footnote strike that.
4	Q. (By Mr. Bentley) I mean, potentially,	4	The Ethicon internal complication rates
5	if there's a document that you didn't see that	5	documents weren't important enough to add a
6	indicated Ethicon had knowledge about complications	6	footnote citation into your report; is that true?
7	associated with Prolift and you didn't review that,	7	MR. KOOPMANN: Object to form.
8	if you had seen that, that could have altered your	8	A. Are you talking about the report or the
9	opinions in this case; isn't that true?	9	reliance list?
10	MR. KOOPMANN: Object to form.	10	Q. (By Mr. Bentley) Doctor, you testified
11	A. It's potentially true. It's	11	that you based your opinions upon some
12	speculative, but maybe.	12	complications data that was provided to you by
13	Q. (By Mr. Bentley) Is it fair to say that	13	Ethicon; is that correct?
14	your opinions in this case are largely based on	14	A. Yes.
15	your own clinical experience and medical literature	15	Q. Okay. And my question is, that
16	you reviewed?	16	complications data that was provided to you, why
17	A. Yes.	17	was that not cited in your report?
18	Q. And is it fair to say that your opinions	18	A. My report is basically primarily on my
19	in this case are not really related to strike	19	experience and the review of the medical
20	that.	20	literature.
21	Is it fair to say that your opinions in this	21	Q. Thank you.
22	case are not really based on Ethicon's internal	22	Doctor, are all of your opinions contained
23	knowledge or what Ethicon did or didn't do? Is	23	within your report?
24	that a fair statement?	24	A. The overwhelming majority of my
1		1	
25	A. It's not fair.	25	opinions. There may be one I missed or overlooked

Page 22 Page 24 1 that's not in the report, but to the best of my 1 that you decided to include certain articles in 2 2 your report, but based on which articles you knowledge, yes. 3 3 Q. And as you sit here today, you don't thought were important to you; is that fair? 4 have any other opinions that you anticipate 4 A. Yes, that's fair. 5 5 providing to the jury at trial; is that correct? Q. How did you decide not to include an 6 6 article in your report? A. Nothing that I anticipate, correct. 7 Q. Have any of your opinions changed since A. Well, if I had never read it before or 8 no one's ever asked me to read it, that wouldn't be you wrote your report in February -- strike that. 9 included in it. If I did a PubMed research search Have any of your opinions changed since you 10 10 and it didn't come up, then I wouldn't have signed your report in February of this year? 11 A. That's correct. 11 included it, if I felt that it was of low-level 12 12 evidence, if there were some concerns about the Q. And you stand by all of your opinions in 13 13 methods of the article. I tried to choose articles that report? 14 14 A. I do. that supported my opinions, so it's more what I use 15 15 Q. I'd like to explore how you cited to to make my opinions, not what I decided not to use. 16 various articles within your report. 16 Q. So did you make a conscious decision not 17 17 Just generally, how did you choose which to include articles that didn't support your 18 18 opinion? articles you wanted to cite to in your report? 19 19 MR. KOOPMANN: Object to form. A. Those articles, some of those appear in 20 20 A. So I started out with articles that I this report with reference to claims that have been 21 21 was already immediately familiar with, articles made by plaintiffs and plaintiffs' experts, so 22 22 that I had used previously in other types of those articles are -- many of those are included in 23 23 reviews or reports or presentations that I put this report. So I felt that this was a very 24 together, articles that have been important to me 24 balanced report. Naturally, the articles that I 25 long-term over the last 15 years in affecting how I rely on to formulate my opinions are going to be Page 23 Page 25 1 think about prolapse and how I manage it, articles more heavily emphasized. 1 2 2 that had been provided to me for review by others. Q. And you feel it's important to have an 3 As I drafted the article, there were areas 3 objective or balanced approach to presenting your 4 that I felt that I needed to do more research on, 4 opinions here? 5 and articles would then be added in as I saw gaps A. Well, those words kind of are in 6 in the report. And so it was definitely an contradiction of each other, "balanced" and 7 evolving process. It happened in stages. Some of "opinionated." But, you know, I made opinions 8 these articles I've read years ago and reread them 8 based on articles that formulated how I practice, 9 9 and included them. Other ones are articles that how I teach my residents and fellows, how I see 10 10 I've become aware of just more recently. colleagues in the medical community practice, what 11 Q. (By Mr. Bentley) Do you agree that 11 I've witnessed at scientific meetings. So it's a 12 12 there's a large number of articles that exist out process, but I tried to choose the articles that 13 in the public domain that are not cited in your 13 were most impactful. 14 report? 14 Q. You wouldn't want to deliberately just 15 15 not cite to articles that were contrary to your A. I agree that there's certainly articles 16 16 that are not cited in my report. I don't know opinions in this report, would you? 17 17 exactly how many. I'm sure I'm dealing with just a A. There's articles that I'm aware of that 18 18 percentage of articles. I did not cite in this report, whether you want to 19 19 Q. Certainly. And there's a number of call that deliberate or not deliberate. Like I 20 20 articles that are -- strike that. mentioned earlier, the articles that I cite are 21 There's a number of scientific articles that 21 articles that I feel are valuable and supportive of 22 22 are cited in your reliance list that you don't my opinions. discuss in your report; would you agree with that? 23 23 Q. And I believe you mentioned that one way 24 A. I do agree with that, yes. 24 you evaluate the importance of an article is based

25

Q. Okay. So I believe you've testified

25

off of the level of evidence; is that correct?

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	Page 26		Page 28
1	A. Yes, that's one way.	1	provided by Ethicon?
2	Q. Could you please explain what's your	2	A. No, that's not fair.
3	understanding of levels of evidence?	3	Q. Where have you received training
4	A. Yes. And I did reference that. If you	4	specific to Prolift other than through Ethicon?
5	look at the levels of evidence for practitioners,	5	A. From observing colleagues performing the
6	you have Level I evidence, which would be the	6	procedure, from my review of the medical
7	highest level that is systematically used,	7	literature. A lot of overlap with Prolift came
8	meta-analyses and RCTs. And then go all the way	8	from other products or maybe from other prolapse
9	down to the bottom of the pyramid, Level IV would	9	procedures, and so Prolift didn't develop or evolve
10	be, you know, case reports, and so that would be	10	inside a vacuum. It came out of other procedures
11	the lowest level of evidence. In between, you have	11	and devices. So I had extensive knowledge on
12	case series, and then prospective studies that are	12	Gynemesh mesh and Prolene soft mesh well before
13	nonrandomized.	13	Prolift. And so that's it was a process.
14	Q. Okay. And you wouldn't consider your	14	MR. BENTLEY: Okay. I'm going to strike
15	report a systematic review of the totality of	15	that as nonresponsive.
16	literature that exists regarding Prolift, would	16	Q. (By Mr. Bentley) Doctor, my question
17	you?	17	is, other than training you received from Ethicon,
18	A. It's not a systematic review. That's	18	have you received any other training specific to
19	correct.	19	Prolift, formalized training?
20	Q. And likewise, you didn't perform a	20	MR. KOOPMANN: Object to form.
21	meta-analysis here, did you?	21	A. What would you mean by "formalized
22	A. I did not.	22	training"?
23	Q. In fact, you're here relying upon other	23	Q. (By Mr. Bentley) Well, would you define
24	people's systematic reviews and meta-analyses; is	24	for me what you consider formal training?
25	that correct?	25	A. Formal training? Well, I would say
	D 05		
	Page 27		Page 29
1	A. As well as my own personal experience	1	formal training would be something that you
2	with this device.	2	received in your residency or in your fellowship,
3	Q. Doctor, is one of the bases of your	3	something you received a certificate or document
4	opinions here I believe your report states that	4	supporting your hours that you trained on the
5	you're also relying upon your training; is that	5	device. So for instance, with prof ed events,
6	correct?	6	people may come away with a certificate.
7	A. On my training?	7	Formal training is going to be different
8			0 0 0
	Q. Training.	8	depending on who you talk to, but once you finish
9	A. Yes, education, training and clinical	9	depending on who you talk to, but once you finish your residency and fellowship, all physicians in
10	A. Yes, education, training and clinical practice and experience.	9	depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices,
10 11	A. Yes, education, training and clinical practice and experience.Q. During your medical education and	9 10 11	depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices, and that can come from professional medical
10 11 12	 A. Yes, education, training and clinical practice and experience. Q. During your medical education and subsequent training, when did you first become 	9 10 11 12	depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices, and that can come from professional medical societies, from industry, from colleagues. So
10 11 12 13	A. Yes, education, training and clinical practice and experience. Q. During your medical education and subsequent training, when did you first become exposed to training on Prolift?	9 10 11 12 13	depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices, and that can come from professional medical societies, from industry, from colleagues. So that's how I would define "formal training."
10 11 12 13	A. Yes, education, training and clinical practice and experience. Q. During your medical education and subsequent training, when did you first become exposed to training on Prolift? A. On Prolift? Well, Prolift I became	9 10 11 12 13 14	depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices, and that can come from professional medical societies, from industry, from colleagues. So that's how I would define "formal training." Q. Thank you.
10 11 12 13 14 15	A. Yes, education, training and clinical practice and experience. Q. During your medical education and subsequent training, when did you first become exposed to training on Prolift? A. On Prolift? Well, Prolift I became aware of early in my practice, sometime in around	9 10 11 12 13 14	depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices, and that can come from professional medical societies, from industry, from colleagues. So that's how I would define "formal training." Q. Thank you. Have you received any training specific to
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10 11 12 13 14 15 16	A. Yes, education, training and clinical practice and experience. Q. During your medical education and subsequent training, when did you first become exposed to training on Prolift? A. On Prolift? Well, Prolift I became aware of early in my practice, sometime in around 2003 and 2004. I began clinical practice in 2002 after completing my fellowship. So Prolift was not	9 10 11 12 13 14 15 16	depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices, and that can come from professional medical societies, from industry, from colleagues. So that's how I would define "formal training." Q. Thank you. Have you received any training specific to Prolift from any of the professional medical societies?
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10 11 12 13 14 15 16 17 18	A. Yes, education, training and clinical practice and experience. Q. During your medical education and subsequent training, when did you first become exposed to training on Prolift? A. On Prolift? Well, Prolift I became aware of early in my practice, sometime in around 2003 and 2004. I began clinical practice in 2002 after completing my fellowship. So Prolift was not a product that was commercially available when I was a resident or fellow or medical student.	9 10 11 12 13 14 15 16 17 18	depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices, and that can come from professional medical societies, from industry, from colleagues. So that's how I would define "formal training." Q. Thank you. Have you received any training specific to Prolift from any of the professional medical societies? A. I have not. Q. And you previously testified Prolift nor
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10 11 12 13 14 15 16 17 18 19 20 21	A. Yes, education, training and clinical practice and experience. Q. During your medical education and subsequent training, when did you first become exposed to training on Prolift? A. On Prolift? Well, Prolift I became aware of early in my practice, sometime in around 2003 and 2004. I began clinical practice in 2002 after completing my fellowship. So Prolift was not a product that was commercially available when I was a resident or fellow or medical student. Q. When you were a resident or fellow, were there any transvaginal mesh kits available for prolapse?	9 10 11 12 13 14 15 16 17 18 19 20 21 22	depending on who you talk to, but once you finish your residency and fellowship, all physicians in practice look for ways of training on new devices, and that can come from professional medical societies, from industry, from colleagues. So that's how I would define "formal training." Q. Thank you. Have you received any training specific to Prolift from any of the professional medical societies? A. I have not. Q. And you previously testified Prolift nor any of the transvaginal mesh kits for prolapse were available during your residency or fellowship. So other than the training that you've received from

	Page 30		Page 32
1	Q. I believe you testified that you used	1	Ethicon?
2	Gynemesh prior to using the Prolift total repair	2	A. Yes.
3	kit; is that fair?	3	Q. So Ethicon certified that you received
4	A. Yes.	4	the training on its Prolift; is that correct?
5	Q. Did you receive formalized training from	5	A. They gave me a certificate, yes.
6	Ethicon on the Gynemesh?	6	Q. Did your hospital require you to present
7	A. No.	7	the certificate to be allowed to use the Prolift
8	Q. Have you used any other total repair	8	kit?
9	kit repair mesh kits for prolapse?	9	A. No, they did not.
10	A. I think Ethicon had the only total kit	10	Q. So what purpose strike that.
11	in terms of a total Prolift, but I used the	11	What utility did you get from the prof ed
12	anterior kit and the posterior kit by American	12	certificate regarding Prolift, if any?
13	Medical Systems, the Elevate kit specifically.	13	A. I didn't feel the need to have the
14	Q. When did you use the AMS anterior and	14	certificate. They just provided it to people who
15	posterior kits?	15	attended the course and actively participated and
16	A. I didn't use them very often, probably	16	completed the course, so I went and watched another
17	less than 20, but that would have been in and	17	surgeon do a number of Prolift cases and then had
18	around 2007, 2008, maybe later, 2009, but it	18	reviewed the prof ed material that was provided to
19	•	19	me, and we received some lectures, and then also
	wasn't I didn't do very many of those kits.		attended a cadaver course.
20	Q. That was after you had been using	20	
21	Prolift?	21	Q. Is it fair to say that the certificate
22	A. The same time. I never stopped using	22	just certifies your attendance at the prof ed
23	Prolift. There was one particular hospital that	23	activity?
24	only had the AMS product, and so I did use it	24	A. No, that's not fair.
25	there.	25	Q. Was there some sort of a test or
	Page 31		Page 33
1	Q. Did you receive formalized training from	1	evaluation at the end of the prof ed activity that
2	AMS regarding their products for prolapse?	2	you had to complete to receive a certification?
3	A. Again, the word "formalize" is difficult	3	A. There was no test.
4	to characterize. But what I received from American	4	Q. What was the strike that.
5	Medical Systems were PowerPoint presentations,	5	What did you have to do to receive the
6	videos, brochures, IFUs, things of that matter.	6	certificate from Ethicon for the Prolift prof ed
7	MR. KOOPMANN: Can we go off the record one	7	training activity?
8	second?	8	A. It would depend on who the individual
9	(Discussion held off the record.)	9	was and what their level of training was. There
10	Q. (By Mr. Bentley) Doctor, we were	10	was essentially three pathways to training. One
11	discussing training, and you mentioned that some	11	pathway was from someone who was very experienced
12	training that's available on products could be	12	with prolapse kits and maybe were transitioning
13	professional education activities; is that correct?	13	from one type of kit to another. Then there was
14	A. Correct.	14	the intermediate person who was very experienced in
15	Q. And sometimes those prof ed or	15	procedures that were similar in terms of
16	professional education activities provide a	16	graft-augmented repairs and trocar-based repairs.
17	certificate of completion at the end; is that	17	And then there was the surgeon who was doing
18	correct?	18	primarily native tissue repairs. And so each one
19	A. Yes.	19	of those individuals needed a different level of
	Q. Have you ever received a certificate for	20	training.
20	Q. 114 to you ever received a certained for		
20 21	training related to Prolift?	21	Q. And who would determine what level of
		21 22	Q. And who would determine what level of training was appropriate for that doctor based on
21	training related to Prolift?		
21 22	training related to Prolift? A. Yes.	22	training was appropriate for that doctor based on

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	Page 34		Page 36
1	and what they felt their needs were.	1	education manager, the person who arranged the
2	Q. And then based off of that individual's	2	event, so each one of these events had to be
3	personal assessment, they would attend whatever	3	scheduled and arranged and attended by an Ethicon
4	training they felt was appropriate; is that	4	personnel. They were never done in isolation in
5	correct?	5	absence of Ethicon personnel.
6	A. There was a dialogue between the trainee	6	Q. I think I've seen some brochures for the
7	and the professional education manager and	7	training program.
8	physicians that attended the courses, and so	8	So typically how long would a Prolift
9	there's constant feedback that was provided in both	9	training program have been?
10	directions. You would ask the individual what	10	A. I've seen some last as long as a few
11	procedures have they done currently, what have they	11	days, others a few cases. It would just depend on
12	done in the past, what things they're comfortable	12	whether or what level that person was at. And
13	what, what things would they like to learn more	13	then there was a lot of self-study that was
14	about.	14	required before they attended the course before
15	Q. And the professional education manager,	15	they would be allowed to attend the course. So I
16	that would be someone working on behalf of Ethicon	16	can't say the exact hours. I can tell you what my
17	to teach about the Prolift product?	17	own experience was and how many hours I spent
18	A. That's correct.	18	training on Prolift.
19	Q. And you actually taught on Prolift; is	19	Q. I'd appreciate that.
20	that correct?	20	You're presenting opinions in your report
21	A. I did.	21	about the adequacy of the training that was
22	Q. And in your experience teaching as a	22	provided; is that correct?
23	preceptor for the Prolift product, did you	23	A. Yes.
24	encounter that difference doctors had different	24	Q. And you're basing that upon your own
25	experience in using transvaginal mesh placement for	25	personal experience; is that correct?
	Page 35		Page 37
1	treating prolapse?	1	A. Both as a trainee and a trainer.
2	A. Yeah, I encountered all three levels	2	Q. So if, for example, there was a training
3	that I described there of physicians.	3	session for Prolift that was scheduled for, say,
4	Q. And did you have some test inside your	4	eight hours, would you expect that that full eight
5	head that you had strike that.	5	hours would be actually completed by the person in
6		1	
7	Did you have some requirement in your head	6	attendance to receive the certificate?
	that you had to think about before you would give	6 7	A. They had to complete the course, yeah.
8	that you had to think about before you would give this person a certificate of completing the		A. They had to complete the course, yeah. And I don't know who provided the certificate, but
	that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed	7 8 9	A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the
8 9	that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed the training program that they felt was appropriate	7 8	A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the course attended all of the course, from start to
8 9 10 11	that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed the training program that they felt was appropriate and you certified that they attended that?	7 8 9	A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the course attended all of the course, from start to finish.
8 9 10 11 12	that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed the training program that they felt was appropriate and you certified that they attended that? A. I was one of the teachers, but I was not	7 8 9 10	A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the course attended all of the course, from start to finish. Q. So you've testified and disclosed in
8 9 10 11 12	that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed the training program that they felt was appropriate and you certified that they attended that? A. I was one of the teachers, but I was not anybody that provided grades or a certificate or	7 8 9 10 11 12 13	A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the course attended all of the course, from start to finish. Q. So you've testified and disclosed in your report that another basis for your opinions is
8 9 10 11 12	that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed the training program that they felt was appropriate and you certified that they attended that? A. I was one of the teachers, but I was not anybody that provided grades or a certificate or recommendations on who got the certificate. That	7 8 9 10 11 12	A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the course attended all of the course, from start to finish. Q. So you've testified and disclosed in your report that another basis for your opinions is your personal experience treating patients; is that
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8 9 10 11 12 13 14 15 16 17 18	that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed the training program that they felt was appropriate and you certified that they attended that? A. I was one of the teachers, but I was not anybody that provided grades or a certificate or recommendations on who got the certificate. That wasn't something that I was part of the decision-making on. Q. Did you strike that. Was there someone present from Ethicon who would record who was in attendance at the training activity?	7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the course attended all of the course, from start to finish. Q. So you've testified and disclosed in your report that another basis for your opinions is your personal experience treating patients; is that correct? A. Yes. Q. Approximately how much of your time is spent treating patients? A. I spend about 85 percent of my time in my clinical practice, which would include doing
8 9 10 11 12 13 14 15 16 17 18 19 20 21	that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed the training program that they felt was appropriate and you certified that they attended that? A. I was one of the teachers, but I was not anybody that provided grades or a certificate or recommendations on who got the certificate. That wasn't something that I was part of the decision-making on. Q. Did you strike that. Was there someone present from Ethicon who would record who was in attendance at the training activity? A. Record who was there?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the course attended all of the course, from start to finish. Q. So you've testified and disclosed in your report that another basis for your opinions is your personal experience treating patients; is that correct? A. Yes. Q. Approximately how much of your time is spent treating patients? A. I spend about 85 percent of my time in my clinical practice, which would include doing surgery and seeing patients in the clinic. While
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	that you had to think about before you would give this person a certificate of completing the training program, or was it simply they completed the training program that they felt was appropriate and you certified that they attended that? A. I was one of the teachers, but I was not anybody that provided grades or a certificate or recommendations on who got the certificate. That wasn't something that I was part of the decision-making on. Q. Did you strike that. Was there someone present from Ethicon who would record who was in attendance at the training activity? A. Record who was there? Q. Yes.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. They had to complete the course, yeah. And I don't know who provided the certificate, but my general observation was people who attended the course attended all of the course, from start to finish. Q. So you've testified and disclosed in your report that another basis for your opinions is your personal experience treating patients; is that correct? A. Yes. Q. Approximately how much of your time is spent treating patients? A. I spend about 85 percent of my time in my clinical practice, which would include doing surgery and seeing patients in the clinic. While I'm seeing patients in the clinic and doing

	Page 38		Page 40
1	practice.	1	time, so at least for the last ten years it's
2	Q. And can you approximate how much of your	2	between 400 and 500 cases per year. And that would
3	time is spent in surgery versus in clinic?	3	include, you know, major procedures. I'm not
4	A. It's about 50/50. In a 20-day rotation,	4	including minor procedures that I perform in the
5	I spend 11 days in surgery and nine days in the	5	office.
6	clinic.	6	Q. Would the minor procedures include
7	Q. And then of your time performing	7	simple excision of mesh erosion?
8	surgery, approximately how much of that is treating	8	A. It would not.
9	prolapse?	9	Q. You would consider that a more
10	A. I don't have an exact number, but about	10	complicated case, using your characterization?
11	50 percent of the time I'm treating men and 50	11	A. I would separate what I do in the office
12	percent of the time I'm treating women. And so of	12	versus what I do in the operating room, so the
13	the 50 percent of the time I'm treating women, that	13	minor procedures I do in the office would include
14	would deal with incontinence and prolapse and other	14	transurethral bulking agents, cystoscopies,
15	female pelvic floor disorders.	15	urodynamics, suprapubic catheter placement,
16	Q. Do you have an estimate how much of your	16	urethral dilations. Those are the procedures that
17	time treating women is spent between incontinence	17	are in that category for office procedures.
18	versus prolapse?	18	Q. Do you perform any mesh-trimming
19	A. There would be a greater percentage with	19	procedures in the office?
20	incontinence.	20	A. Very rarely. I have in the past, and I
21	Q. And then you also see patients for	21	might trim a suture, but not mesh. I did that for
22	complications related to mesh; is that correct?	22	a very brief time and reported on that, and I
23	A. I see patients with complications from	23	didn't find that to be effective, so I stopped
24	urogynecologic surgery.	24	doing that.
25	Q. Other doctors refer more complicated	25	Q. When you say it was ineffective, would
	Page 39		Page 41
1	cases to you for mesh complications sometimes; is	1	there be a recurrence of the erosion?
2	that fair?	2	A. Yeah, the recurrence rate was more than
3	A. All sorts of complications.	3	50 percent. It didn't mean that all those patients
4	Q. Do you feel that you're referred simple	4	were symptomatic, but it wasn't effective, so we
5	complications also?	5	went to an excision in the operating room.
6	A. Yes.	6	Patients were more comfortable, certainly, when we
7	Q. Do you have an estimate of the time	7	did that.
8	spent treating women of how much of your time is	8	Q. Do you have an estimate of how many
9	spent treating complications related to mesh?	9	surgeries you do per year to treat prolapse?
10	A. In terms of number of cases I do per	10	A. To treat prolapse, probably somewhere
11	year?	11	anywhere between 50 and 100. It would depend on
12	Q. Sure.	12	the particular year.
13	A. I do somewhere around 35 to as much as	13	Q. And you've used a number of different
14	45 cases per year.	14	procedures to treat prolapse based on the specific
15	Q. Treating complications related to a mesh	15	patient; is that correct?
16	product?	16	A. That's correct.
	A. Yes.	17	Q. When you were using Prolift, do you have
17	Q. Approximately how many surgeries do you	18	an idea of how many Prolift procedures you were
17 18			doing per year?
		19	
18 19	perform a year?		
18 19 20	perform a year? A. About 500.	20	A. I have a total. I don't have a
18 19 20 21	perform a year? A. About 500. Q. Has that been pretty consistent	20 21	A. I have a total. I don't have a breakdown based on year, but if you include Prolift
18 19 20 21 22	perform a year? A. About 500. Q. Has that been pretty consistent throughout your career?	20 21 22	A. I have a total. I don't have a breakdown based on year, but if you include Prolift and Prolift+M together, I've done close to 200.
18 19 20 21	perform a year? A. About 500. Q. Has that been pretty consistent	20 21	A. I have a total. I don't have a breakdown based on year, but if you include Prolift

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	Page 42		Page 44
1	Q. So you think you've done about a hundred	1	previously that you keep a case log of all of your
2	Prolift and about a hundred +Ms?	2	surgical procedures; is that correct?
3	A. Correct.	3	A. I do.
4	Q. We've previously or strike that.	4	Q. And that would include surgeries where
5	I believe you've previously testified that	5	you implant the Prolift product; is that correct?
6	in incontinence products, there was an evolution of	6	A. Yes.
7	your practice and which products you preferred to	7	Q. Did you review the case log specifically
8	use; is that fair? As we talked about earlier	8	to see how many Prolift procedures you had
9	today, you may have evolved your practice to use	9	performed before you prepared your report?
10	Abbrevo more frequently than an obturator, the	10	A. I did.
11	TVT-O full sling; is that correct?	11	Q. So you got an exact number of how many
12	A. That's correct.	12	Prolift products you had implanted?
13	Q. Did you have a similar evolution in your	13	A. I had an approximate number. I mean,
14	preferred product to treat between using Prolift	14	the case log is nearly complete. I prepare that,
15	versus Prolift+M?	15	for the most part, prospectively, but sometimes
16	A. Yes.	16	cases get cancelled or rescheduled and they may or
17	Q. And what was that preference?	17	may not appear on my case log. So I would say it's
18	A. Well, when Prolift+M became available,	18	mostly accurate.
19	as I mentioned earlier in the other deposition, I	19	Q. Is it fair to say that your case log is
20	tend to be a new adopter, or early adapter of	20	one of the bases for your opinions in this case?
21	procedures. And so similar for the +M. I was very	21	A. No, it's just a list of the number of
22	interested in the technology and the biomaterials	22	cases, but I don't need to know how many cases I've
23	of the +M. And the rest of the system looked the	23	done to prepare my opinions.
24	same in terms of the trocars and the sheets, the	24	Q. That's right. Your case log doesn't
25	retrieval devices. And so it seemed very logical	25	track complications for Prolift implants; is that
	Page 43		Page 45
1	to me, intuitive, that it would be a kit that I	1	correct?
2	would want to try.	2	A. My case log doesn't, but I have, you
3	Q. And approximately when did you begin	3	know, reported I have one small study I did on
4	trying the new product in Prolift+M?	4	Prolift where I looked at a small cohort of
5	A. Let me look at my report, but I believe	5	patients that I had treated with Prolift, and that
6	it was around 2007.	6	involved a surgical video, and that study kept
7	(Reviewed document.) So in 2006, excuse me,	7	track of the complications.
8	in 2006, I started using the +M system.	8	Q. When was that study?
9	Q. In 2006, you believe you began using the	9	A. I don't remember the exact date, but I
10	+M system; is that correct?	10	think it was around 2009, maybe 2008 or 2009.
11	A. I'm sorry. 2006 to 2012 is when I used	11	Q. Is it cited in your report?
12	those products. I'd probably say around	12	A. I would have to check. I don't see it
13	probably around 2009 or 2010. Whenever +M became	13	here in my bibliography.
14	available, I immediately started using it.	14	Q. Do you remember what journal it was
15	Q. And once you started using it strike	15	published in, if any?
16	that.	16	A. It was an abstract, so it was in the
17	Once you started using Prolift+M and you	17	Journal of Urology. It was presented at the
18	became comfortable with it, did that become your	18	American Urologic Association meeting. The first
19	preferred prolapse mesh kit?	19	author would be Pshak, starting with the letter
20	A. It did. I used that almost exclusively.	20	P-s-h-a-k, Thomas Pshak. He was one of the
21	There were some exceptions at certain hospitals.	21	residents who worked with me on the project.
22	There was a transition between the two products,	22	Q. And what was the purpose of that study?
23	but eventually it became the only prolapse kit that	23	A. The study was to provide a video to
1		1	<u>.</u>

24

25

Q. Doctor, I believe you've testified

24

25

I used.

inform and educate urologists on the Prolift

procedure, also to perform a short review of our

Page 46 Page 48 1 short-term results with the product. 1 A. The numbers were very small, so it was 2 Q. And when you say one of the goals was to 2 hard to show significant statistical significance, 3 3 but at least the trend was that, yes, the perform a short-term review of your -- strike that. 4 When you say that one of the goals was to 4 double-layer closure seemed to be superior, at 5 5 review your short-term results with the product, least in my hands. 6 6 Q. Would you agree that the erosion rate what was your end point that you were looking at? 7 7 A. The end point? It was a continuous list for the double-layer closure was zero percent while 8 of all the cases that we had performed to date, so 8 the single-layer closure was approximately 15 9 it included our first case, and then the most percent in your study? 10 10 recent case that we did before preparing the A. I'd have to look at the study again, but 11 abstract, so it was as comprehensive as we could 11 that sounds about right in terms of the short-term 12 12 make it. We looked at the outcome in terms of the results. 13 13 Q. And what was the length of follow-up in efficacy and the prolapse resolution rate, and then 14 we looked at the side effects or complications, 14 that study? 15 15 such as stress urinary incontinence, mesh exposure, A. Again, it was fairly short, probably 16 mesh perforation into the lower urinary tract. 16 less than a year. 17 17 Q. Do you know if that study is included in Q. With the Prolift procedure that's 18 18 discussed in the IFU, does that recommend a these binders that you brought today? 19 A. It's on the USB. I know for sure it's 19 single-layer closure or a double-layer closure? 20 20 A. I don't believe the IFU makes on the USB, both the video as well as the abstract. 21 21 Q. And do you know what the long-term recommendations on how to close the surgical wound. 22 22 follow-up was? That's up to the discretion of the physician. Most 23 23 A. No, we don't have long-term follow-up. physicians, including myself, would close the 24 Q. What was the follow-up in the study that 24 wound, you know, the way they were taught to. 25 25 you presented? Q. But in your study, you demonstrated that Page 47 Page 49 A. It was minimal. It was less than a the double-layer closure was much more -- was much 1 1 2 2 safer because it had a lower erosion rate; is that year. 3 3 Q. All right. So other than that abstract correct? 4 that you presented, did you do any other formal or 4 MR. KOOPMANN: Object to form. 5 systematic review of your case log regarding the A. What I mentioned, that there was a trend 6 Prolift patients that you had operated on? 6 towards better results in that group, but it was a 7 A. There was a second abstract that small group with a short-term follow-up, so . . . 8 8 Q. (By Mr. Bentley) Do you know if some compared healing abnormalities in two groups of 9 9 patients, patients that had a single-layer closure, doctors are trained to use a single-layer closure? 10 meaning we closed the vaginal wall just with one 10 A. That's how most people are trained. The 11 11 single-layer closure can involve an interrupted continuous suture, versus patients that had a --12 12 what we call a double-layer closure, so we closed technique, a running technique, a running locking technique. It can involve an absorbable suture 13 13 two separate layers of the vaginal wall, the deep 14 fibromuscular tissue and then the vaginal 14 versus a delayed absorbable suture. Some people 15 15 will trim the vaginal wall, others won't. There's epithelium. 16 16 quite a bit of variability in wound closure Q. Why was that study performed? 17 17 A. I felt that a lot of the healing techniques. 18 18 abnormalities were due to inadequacies in wound Q. And based on your experience that, you 19 19 closure leading to wound dehiscence. So wound know, there's variability in how people are closing 20 dehiscence will lead to mesh exposure. And so my 20 the wound, you did a study to determine whether 21 thought was that if we can replicate what we do in 21 there was a difference in safety based off of a 22 22 other surgeries with the multi-layer-closure single-layer closure versus double-layer closure; is that correct? 23 technique, we can decrease the incidence of mesh 23 24 24 A. The only end point in the study was the exposure.

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Q. And did the study show that?

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exposure rate. We didn't look at other factors in

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1	terms of safety, but it was just looking at	1	know, exam from head to toes primarily focusing on
2	exposure.	2	the abdomen and pelvis and the areas that the
3	Q. Would you consider exposure a safety	3	surgery was performed in. I check the prior
4	issue?	4	surgical incisions. I check the entire vaginal
5	A. I would consider it a complication. And	5	wall. I look at the cervix, if that's present. I
6	most people would consider complications, you know,	6	look at the urethra. I test their urine. I
7	not safe.	7	measure their postvoid residual. And then based on
8	Q. And exposure obviously can affect the	8	that initial assessment, I determine if other tests
9	patient's quality of life; isn't that correct?	9	are necessary to evaluate.
10	A. Yeah, that's correct.	10	After a year, I ask them if they have other
11	Q. And your study demonstrated that the	11	providers that they're seeing, if they have someone
12	exposure rate or quality of life was affected based	12	who's performing their annual gynecologic exam, to
13	upon using the double-layer closure; is that	13	ask that person if they're comfortable continuing
14	correct?	14	to follow the patient and include that in their
15	A. That's not correct. We never had any	15	exam. And if they do have someone local, then I
16	quality-of-life data in the study or qualified	16	would see if they're comfortable following up with
17	questionnaires in the study.	17	that patient. If not, then they'll continue to
18	Q. So you think that	18	follow with me.
19	Do you think that Ethicon should have shared	19	Q. That's a fairly extensive list of data
20	with doctors your study results?	20	points.
21	A. No.	21	Do you track those data points in any type
22	Q. Do you think that patients would like to	22	of systematic way, or database?
23	have a decreased erosion rate based off of a	23	A. No, they get entered into the electronic
24	double-layer closure instead of a single-layer	24	record. If we elect to perform a study, a
25	closure?	25	retrospective study looking at a particular
	Page 51		Page 53
1	A. I can't say what it's based on, but	1	problem, then the data will be then organized, so
2	patients would prefer to have less complications,	2	the data is being put into the electronic record
3	yes. That's obvious. Getting into how we close	3	but not always collected or retrieved or organized
4	the wound, that's not something I ever really	4	or summarized.
5	discuss with patients.	5	Q. And is that how you performed or is
6	Q. Doctor, when you want to go back and	6	that how you collected the data for your two
7	look at your patients to see how, you know, your	7	abstracts that we just discussed? You went back
8	Prolift patients have how they have healed up to	8	and looked at their electronic record; is that
9	see who had erosions or complications or who's	9	correct?
10	doing good, how do you perform that analysis on	10	A. That's correct.
11	your patients, or on your patient data?	11	Q. Okay. And other than those two
12	A. So most patients I tend to see at two	12	abstracts, have you gone back and reviewed the
13	weeks postop, at six weeks postop, three months	13	some of the electronic data available regarding
14	postop, and a year. During each one of those	14	your Prolift patients other than those two
15	visits I perform a history and physical exam, and I	15	abstracts?
16	ask them very pointed questions on how they're	16	A. Since the FDA Public Health
17	doing. Are they satisfied? Are they having any	17	Notification, the FDA has asked physicians to keep
18	issues with incontinence or prolapse? Are they	18	track of that. So if someone comes in with a
19	having issues with infection? Are they having	19	complication, then I would keep track of that, yes.
20	issues with pain or sexual dysfunction? I ask them	20	But I'm not calling people, you know, after a year
21	if they're satisfied, if they're glad they did the	21	or sending out a mailing or anything like that. So
22	procedure and had the procedure done. Are there	22	if they're coming into my office with a complaint,
23	other things that they're concerned about? And	23	or if another provider's seeing my patient and
24	those are the questions.	24	there's a complaint, then I would have awareness of
25	The physical exam would include a full, you	25	that.

Page 54 Page 56 1 Q. Okay. And I may have not asked a good 1 A. Yes. 2 question. Q. Before the break, we were talking about 3 3 Other than those two abstracts that you've your case log, and I just wanted to wrap up -- I 4 just discussed, have you gone back and reviewed the 4 was asking -- I believe you testified that you 5 data that you have in the electronic records for 5 didn't do any type of systematic review of your 6 6 case log to prepare for your Prolift report; is your patients where you've implanted a Prolift? 7 7 Have you done any type of systematic review of that that true? 8 data since those two abstracts? 8 A. That's correct. 9 9 A. I have not. Q. And likewise, you didn't do any type of 10 Q. Does your case log track patients that 10 systematic review of your case log for your 11 are referred to you from other doctors to treat 11 Prolift+M patients to prepare for that report 12 12 mesh-related complications? either; is that true? 13 13 A. I don't know if "track" would be the A. Correct. 14 right word, but, you know, when we visit with them, 14 Q. And so in reaching your opinions in this 15 we do the best we can to obtain the prior operative 15 case, you're not relying upon any type of 16 report, and we will make a notation of what product 16 systematic review of your own case log to reach 17 17 they had put in previously, whether they're doing your opinions here; is that fair? 18 well or not well. So it's part of our general 18 A. That's fair. 19 intake. 19 Q. And similarly, you're not relying on any 20 20 When someone comes in with any disease type of systematic review of the patients you've 21 21 process, we ask them if they've had prior treated for erosion or other complications in 22 22 surgeries. What are those surgeries. We try to reaching your opinion here; is that fair? 23 23 get as much detail as we can, including the A. I did mention the one study before the 24 operative reports on those surgeries, especially if 24 break recently that we looked at 82 complications 25 25 we're going to plan on doing another surgery in a that we had managed related to prolapse kits, so Page 55 Page 57 similar area. that certainly affects my opinion and my thoughts 1 1 2 2 Q. I think we've previously discussed, your on this process. 3 3 case log doesn't necessarily track all of that Q. Sure. Other than that, you haven't done 4 information; is that correct? 4 any type of systematic review of the complications 5 A. The case log doesn't. Again, it would 5 you've treated, such as erosion, in preparation for 6 come back to doing a specific study. The study I 6 your report or in preparation for this deposition; 7 didn't mention was one that was presented last is that fair? 8 spring at the American Urologic Association where 8 A. Well, in that review, there's the whole 9 9 we looked at 82 complications from prolapse kits review, the whole -- it's not a review, it's an 10 that we had managed. 10 abstract. But in the abstract, it focuses on what 11 11 we did to manage those patients and what techniques Q. Okay. 12 12 A. And Dr. Kirk Anderson, who was my fellow worked and what didn't work. at the time, he had presented that data, those 82 13 13 Q. And that abstract's not going to present 14 patients that we managed. The overwhelming 14 some type of erosion rate such that you're going to 15 15 majority of the patients had been referred to me. be able to testify based off that abstract what 16 16 Some of the patients were my own patients. percentage of the patients you treated had an 17 17 MR. BENTLEY: Are we at a good point for erosion; is that fair? 18 lunch? Is that right? I think we're about an hour 18 A. What patients I implanted? 19 19 in. Is that right? Q. Sure. 20 MR. KOOPMANN: Let's go off the record for a 20 A. Yeah, correct. It won't -- it doesn't 21 second. 21 reflect my own personal exposure rate on patients I 22 22 (Recess taken from 12:58 p.m. until implanted. 23 1:08 p.m.) 23 Q. And you can't calculate from that 24 Q. (By Mr. Bentley) Doctor, we're back 24 abstract an erosion rate for other doctors; is that 25 25 from a quick break. Are you ready to go? fair?

	DITAIL FI	уши,	M.D.
	Page 58		Page 60
1	A. Correct.	1	Q. Okay. I appreciate that, but my
2	Q. Doctor, we have briefly discussed a	2	question was a little different, Doctor.
3	little bit, and I believe you mentioned that	3	Is it fair to say that you didn't have some
4	another bases for your opinions in this report is	4	type of systematic approach to how you searched
5	the body of medical literature out there; is that	5	PubMed for articles in preparing your report?
6	true?	6	A. Correct.
7	A. Yes, that's true.	7	Q. Okay. And likewise, did you perform any
8	Q. And I think you mentioned that you've	8	type of systematic search on PubMed to find
9	performed PubMed searches to identify articles	9	articles related to Prolift+M in preparing that
10	regarding prolapse and Prolift; is that true?	10	report?
11	A. That's true.	11	A. I did the same type of search for
12	Q. And did you perform a PubMed search in	12	Prolift and Prolift+M.
13	preparation for reaching your opinions in this	13	Q. And subsequent to issuing your reports,
14	case?	14	have you done any type of systematic search on
15	A. I did.	15	PubMed in preparation for the deposition today on
16	Q. And do you know what the keyword	16	Prolift or Prolift+M?
17	searches you used to perform that search?	17	A. Since issuing these reports?
18	A. I used the word "Prolift."	18	Q. Yes.
19	Q. Okay.	19	A. No, I have not.
20	A. "Mesh," "mesh kit." I believe that was	20	Q. I would assume it's your general
21	it. Probably just those two words.	21	practice to read very scientific articles that are
22	Q. Do you have an idea of how many articles	22	published that concern your practice; is that fair?
23	that search would have returned?	23	A. Yeah, there's a number of journals that
24	A. With respect to the prolapse search, I	24	I read commonly. We have a journal club that's
25	would think somewhere around 30 or 40 articles.	25	part of our practice. We do that at least a few
	Page 50		Dec. (1
1	Page 59 Oftentimes the word "Prolift" doesn't appear in the	1	Page 61 times a year at the University of Colorado with our
2	title even though the article is specifically about	2	residents and students, and so I am a reviewer for
3	that product.	3	a number of journals, so sometimes articles will be
4	Q. I think I misunderstood.	4	sent to me as a reviewer, so I am looking at the
5	Is it your testimony that you performed two	5	medical literature very commonly.
6	different PubMed searches, one using the keyword	6	Q. Do those journal club activities
7	"Prolift" and maybe a second keyword search using	7	discuss, say, mesh-related articles?
8	the key words "mesh kit"? Is that accurate?	8	A. They do. We just discussed one recently
9	A. I'm not certain if that's accurate, but	9	a few weeks ago.
10	I know I recalled doing a PubMed search. The exact	10	Q. When, approximately, was the last
11	key words I used, I know I would have at least used	11	journal club that you attended?
12	those two words. I may have used other words, or	12	A. That would have been two weeks from
13	similar words.	13	tomorrow.
14	Q. It's fair to say that you didn't have	14	Q. And I believe you just testified that
15	any type of systematic approach to how you were	15	you do or you attend journal clubs approximately
16	performing your PubMed search; is that true?	16	quarterly; is that fair?
17	A. Usually when you put in a search word,	17	A. I would say there's at least five or six
18	you'll get some articles, and then they'll show	18	a year that I attend.
19	articles in the column on the right of that that	19	Q. Okay. So subsequent to issuing your
20	are similar to those articles, and it kind of just	20	report on February 26, how many journal clubs have
21	leads you to deeper searches. So you put in that	21	you attended?
22	search word, and you end up looking at a lot of	22	A. Since February?
23	different articles maybe that aren't immediately	23	Q. Yes.
" "		"	
2.4	from that first search word, but it's sort of a	24	A One or two
24	from that first search word, but it's sort of a chain reaction once you start looking at PubMed.	24 25	A. One or two.Q. Okay. And did those journal clubs

Case 2:12-md-02327 Document 2855-8. Filed 09/19/16 Page 18 of 61 PageID #: 104092 Brian Flynn, M.B. Page 62 Page 64 1 identify any important new mesh-related articles 1 evidence and support. The reports that we were 2 that you felt changed or affected your opinions in 2 talking about earlier, my small case series of the 3 this case? 3 double-layer closure and the Prolift video, those 4 A. Well, one article that had come up in my 4 were low-level evidence. Some people call them 5 pilot studies or case series. We do those studies last deposition was the Welk article from Canada. 6 It was a JAMA article, so that was one that -- JAMA as way of encouraging scientific research by our 6 7 is a very large journal that has high readership, residents and fellows. It gives them an 8 and so we felt that that was important to review. 8 opportunity to present. But I don't rely on those 9 Q. Would you expect that attending these 9 as heavily as I do on systematic reviews and the 10 10 journal clubs would keep you apprised of the meta-analyses. 11 important literature that's being put out there 11 Q. Would you agree that all of the articles 12 12 regarding your practice and, specifically, Prolift that you have cited in your paper are all from 13 13 and mesh kits? authors that you respect? 14 14 A. It's one of many ways. It's part of the A. No, I wouldn't agree with that. 15 15 process, that as well as attending scientific Q. Are there certain authors that you've 16 meetings and discussion with colleagues, my own 16 cited to that you don't respect in your paper? 17 personal review of the literature in the journals 17 A. I think that would be too strong of a 18 18 that I subscribe to. word. I mentioned they're some of the authors I 19 19 Q. When you're reviewing these scientific know, but I would say overwhelmingly I don't know 20 20 articles regarding Prolift and mesh kits for the majority of these authors personally, so I can 21 21 treating prolapse, is it fair to say that there's say there's a number of authors that I have a 22 22 strengths and weaknesses with any given article? personal relationship with that I know, I've met, 23 23 I've had personal communication with, but 90 24 Q. Can you describe for me what strengths 24 percent of these authors I've never or I never will 25 you would look for in an article to use to reach 25 meet, so it's hard for me to say if I respect them Page 63 Page 65 1 your opinions in this case? 1 or not. 2 2 A. Well, we usually start out by looking at Q. Aside from the strengths that you just 3 3 the pure size of the article, how many patients described, are there any weaknesses that you look 4 were enrolled. Then we look at the methods. Was 4 out for that might discount an article other than 5 this prospective or retrospective? Were patients the lack of the strengths that we just discussed? 6 randomized? Was there more than one center A. Okay. So if it wasn't in a 7 involved, maybe more than one surgeon involved? peer-reviewed journal, I'm concerned that maybe 8 they've attempted to publish it in a peer-reviewed Those things factor into what we consider levels of 9 9 evidence. Was it an actual study where patients journal and it was turned down, so they went to a

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were enrolled, or is it more of a review, systematic review or meta-analyses?

So we look at the number of patients, the format of the study. We look at what journal it was published in to see if the journal was peer reviewed. That's also important.

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Sometimes I might know the authors. People that I know, I tend to follow. And, you know, I'm interested in reading what they have to write, my mentors, especially, and thought leaders that I respect in SUFU and AUGS. So it's a process. But briefly, that's the process that I adhere to.

O. Do you feel that the articles that you cited in your report met those tests for whether an article is strength -- or has strength?

A. Well, the report has various levels of

second- or third-tier-level journal, so that's something that may be a red flag, although, occasionally, you'll find very good articles in journals that aren't peer reviewed. It's quite variable. Just the whole opposite of what I just said. If it's small numbers, if it's not multi-center, if it's not randomized, if there's not long-term follow-up, you know, those are going to be weaknesses.

Q. Right. So other than the lack of the strengths that we've discussed, there's no -- you can't identify right now any weaknesses that you look out for other than the strengths or the lack of strengths that we just discussed?

A. Well, getting back to the journals, if it's not a peer-reviewed journal, that's considered

	Page 66		Page 68
1	a weakness. If the follow-up is short, that's a	1	reviews. I understand incidence and prevalence and
2	weakness.	2	epidemiologic factors.
3	Q. Generally, what follow-up are you	3	Q. Sure.
4	looking for when you're evaluating a study that's	4	A. So it's really not up to me to decide if
5	discussing Prolift and mesh kits to treat prolapse?	5	I'm an expert, but I think I do provide expertise
6	A. Well, I look primarily at how long the	6	in those areas when discussing papers with my
7	procedure's been performed over how many years. So	7	patients, with my residents, the fellows and
8	if the procedure's only been available for a year,	8	students that I educate.
9	then I'm very interested in looking at the	9	Q. You don't publish on epidemiological
10	short-term follow-up, because that's all you're	10	practices; is that fair?
11	going to get. That's the best available	11	A. Not on practices, but it includes
12	information that's available to you. TVT product	12	it's in almost every article we write. That's
13	has been available for since 1998, so it doesn't	13	always in the introduction. There's going to be a
14	make sense for me to look at a study that has less	14	short blurb on epidemiology of the disease, the
15	than, say, three- to five-year follow-up, so the	15	prevalence of the disease, who it affects, you
16	longer the product's on the market, the more you're	16	know, so that people understand the magnitude of
17	going to rely on long-term follow-up. For newer	17	the problem.
18	products, the best you can rely on is short-term	18	Q. Of course. And you've never published
19	follow-up or intermediate follow-up.	19	in any journals like statistics or epidemiology,
20	Q. Right. And my question was specific to	20	right?
21	Prolift and mesh kits to treat prolapse.	21	A. On the mathematical methods?
22	What follow-up are you looking for to	22	Q. Right.
23	evaluate whether a study has the strength that you	23	A. No, I have not.
24	need to rely upon it for your report?	24	Q. Of course.
25	A. I'd like to see a minimum of one year.	25	Okay. Now, I think you testified that you
	Page 67		Page 69
1	And ideally, I'd like to see three years or more.	1	rely upon the studies as presented; is that fair?
2	Q. When you're evaluating the strengths and	2	A. I would need more information on that
3	weaknesses of various articles and ultimately	3	one.
4	reaching a decision of whether or not you're going	4	Q. Okay. For instance, if there was a
5	to include it in your report, is it fair to say	5	problem with some of the measurements in obtaining
6	that you're not performing any type of	6	the data for a study, you wouldn't know that
7	epidemiological analysis on the numbers presented	6 7	the data for a study, you wouldn't know that because you're not getting the patient-level data
7 8	epidemiological analysis on the numbers presented in the case? Is that fair?	6 7 8	the data for a study, you wouldn't know that because you're not getting the patient-level data for the study; is that fair?
7 8 9	epidemiological analysis on the numbers presented in the case? Is that fair? A. I'm not performing the study. I'm only	6 7 8 9	the data for a study, you wouldn't know that because you're not getting the patient-level data for the study; is that fair? A. I don't think I can respond to that. If
7 8 9 10	epidemiological analysis on the numbers presented in the case? Is that fair? A. I'm not performing the study. I'm only reviewing the study, so it's really up to the	6 7 8 9	the data for a study, you wouldn't know that because you're not getting the patient-level data for the study; is that fair? A. I don't think I can respond to that. If you can repeat that again. I'm sorry.
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7 8 9 10 11 12 13	epidemiological analysis on the numbers presented in the case? Is that fair? A. I'm not performing the study. I'm only reviewing the study, so it's really up to the author on how they design the study. Then I look at that study, and I use that as the basis of my opinions in this report.	6 7 8 9 10 11 12	the data for a study, you wouldn't know that because you're not getting the patient-level data for the study; is that fair? A. I don't think I can respond to that. If you can repeat that again. I'm sorry. Q. Sure. For example, if there was a problem with the reliability of the POPQ measurement in a study, would you want to know that
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	epidemiological analysis on the numbers presented in the case? Is that fair? A. I'm not performing the study. I'm only reviewing the study, so it's really up to the author on how they design the study. Then I look at that study, and I use that as the basis of my opinions in this report. Q. Right. So you're not performing any type of follow-up, epidemiological or statistical analysis on the study. You're just taking the study as presented and deciding whether or not it meets your inclusion criteria for your report; is that fair? A. Yeah, that's fair. Q. And, in fact, you're not an expert in doing epidemiological analysis; is that fair?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the data for a study, you wouldn't know that because you're not getting the patient-level data for the study; is that fair? A. I don't think I can respond to that. If you can repeat that again. I'm sorry. Q. Sure. For example, if there was a problem with the reliability of the POPQ measurement in a study, would you want to know that before concluding whether or not that study was reliable upon which you could reach your opinions? A. I have no reason to believe the POPQ wouldn't be reliable. It's something that's been well-standardized and utilized in many studies. Q. I'm sorry. If there was a problem with how the POPQ was collected in a specific study and it didn't say that in the publication, you wouldn't know that by
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	epidemiological analysis on the numbers presented in the case? Is that fair? A. I'm not performing the study. I'm only reviewing the study, so it's really up to the author on how they design the study. Then I look at that study, and I use that as the basis of my opinions in this report. Q. Right. So you're not performing any type of follow-up, epidemiological or statistical analysis on the study. You're just taking the study as presented and deciding whether or not it meets your inclusion criteria for your report; is that fair? A. Yeah, that's fair. Q. And, in fact, you're not an expert in doing epidemiological analysis; is that fair? A. I have some expertise in epidemiology.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	the data for a study, you wouldn't know that because you're not getting the patient-level data for the study; is that fair? A. I don't think I can respond to that. If you can repeat that again. I'm sorry. Q. Sure. For example, if there was a problem with the reliability of the POPQ measurement in a study, would you want to know that before concluding whether or not that study was reliable upon which you could reach your opinions? A. I have no reason to believe the POPQ wouldn't be reliable. It's something that's been well-standardized and utilized in many studies. Q. I'm sorry. If there was a problem with how the POPQ was collected in a specific study and it didn't say that in the publication, you wouldn't know that by your review, say, in your journal club of that
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	epidemiological analysis on the numbers presented in the case? Is that fair? A. I'm not performing the study. I'm only reviewing the study, so it's really up to the author on how they design the study. Then I look at that study, and I use that as the basis of my opinions in this report. Q. Right. So you're not performing any type of follow-up, epidemiological or statistical analysis on the study. You're just taking the study as presented and deciding whether or not it meets your inclusion criteria for your report; is that fair? A. Yeah, that's fair. Q. And, in fact, you're not an expert in doing epidemiological analysis; is that fair?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the data for a study, you wouldn't know that because you're not getting the patient-level data for the study; is that fair? A. I don't think I can respond to that. If you can repeat that again. I'm sorry. Q. Sure. For example, if there was a problem with the reliability of the POPQ measurement in a study, would you want to know that before concluding whether or not that study was reliable upon which you could reach your opinions? A. I have no reason to believe the POPQ wouldn't be reliable. It's something that's been well-standardized and utilized in many studies. Q. I'm sorry. If there was a problem with how the POPQ was collected in a specific study and it didn't say that in the publication, you wouldn't know that by

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	Page 70		Page 72
1	and others don't, so it's a stronger study,	1	Q. Okay. And it can be used to gauge
2	generally, if it's a third party, meaning the	2	whether there was recurrence after a woman was
3	person who didn't do the surgery does the POPQ, for	3	treated for prolapse; is that true?
4	instance, like the surgeon's nurse or partner or	4	A. Yes, that's true.
5	physician assistant. And oftentimes surgeons will	5	Q. And going all the way back to my
6	mention that. You'll see that more commonly in	6	hypothetical, if there was a problem at the
7	more recent reports.	7	data-collection level when the doctors were
8	Q. Let me back up.	8	determining the POPQ after they treated the woman
9	Could you define POPQ for me?	9	for prolapse, if there was a problem in that data
10	A. POPQ is the pelvic organ prolapse	10	collection and you didn't know about that, you
11	quantitation score. It's something that had been	11	wouldn't have that information available to you
12	described at least 15 years ago. I remember	12	when you read the study; is that fair? You can't
13	learning about it when I was a fellow at Duke	13	tell patient-level data from most of the studies
14	University. I studied there under George Webster	14	unless the authors put it in there; isn't that
15	and Cindy Amundsen, Allison Widener and other great	15	fair?
16	thought leaders, and so they taught me how to do	16	MR. KOOPMANN: Object to form.
17	the POPQ.	17	A. I mean, the authors will put it in
18	What it involves is using what we call a	18	there, and generally, if it's from a peer-reviewed
19	measuring stick. This looks like a popsicle.	19	journal, we're going to believe it.
20	Sometimes there's markings on a metal stick. And	20	Q. (By Mr. Bentley) Do you know if, during
21	that would be inserted into the vagina and used to	21	the peer review process, if most journals review
22	take measurements, including the total vaginal	22	all of the patient-level data?
23	length, the length of the genital hiatus, the	23	A. No, the reviewers as a reviewer, I
24	perineal body. And then there's points on the	24	can say, when I review papers, I don't see the
25	anterior wall and the posterior wall, AA, AB, PA	25	actual spreadsheets. I see the manuscript. I see
	Page 71		Page 73
1	and PB. And so you end up putting the numbers in	1	tables. I see graphs, figures. If something
2	what looks like a tic tac toe board, you know, so	2	doesn't seem right to us, we'll send it to an
3	you have some cross hairs with nine boxes, and then	3	in-house person for statistical review to make sure
4	you put your measurements in there. The idea is	4	that the statistics make sense if they're using a
5	that's a more scientific way of quantitating	5	complicated statistical model. And then we have an
6	surgical outcomes compared to, say, mild, moderate,	6	opportunity to send feedback to the authors and ask
7	severe prolapse or stage one, two, three, four.	7	them to respond to our comments. And if those
8	So the whole idea of POPQ was to be able to	8	responses are not satisfactory, then we don't
9	get individual measurements in all the different	9	publish the article.
10	compartments. And it's something that's been	10	Q. Sure.
11	popularized and standardized. When I prepared for	11	Doctor, in your career, have you ever been
12	my exam and my certificate and my board	12	involved in writing or preparing warnings for a
13	certification in female pelvic medicine and	13	medical device?
14	reconstructive surgery, I had to learn about POPQ	14	A. Have I ever prepared a warning?
15	and statistics and epidemiology and all these	15	Q. Yes.
16	things. So I learned it as a fellow, and then I	16	A. No. I've prepared a response to a
17	relearned it again when I was preparing for the	17	warning, but I've never written a warning.
18	exam, and I use it in my practice.	18	Q. Do you have an opinion as to what
19	Q. Right. So essentially, it's a way of	19	warnings are required to go into an IFU?
20	measuring the stage of prolapse, is that fair, to	20	A. Yeah, I have some general requirements
21	sum it up?	21	on what the FDA would like to see in an IFU and
22	A. More than just stage. I think it gives	22	other types of literature.
23	you more detail beyond stage than, say, the Baden	23	Q. Okay. Let's break that down.
24	Walker. It tells you which compartments	24	What are your general requirements for what
25	specifically are prolapsed.	25	you expect to be in an IFU regarding warnings?

Page 74 Page 76 1 A. I want to hear if there's information on 1 specific FDA rule as you sit here today? 2 toxicity. I want to hear if there's information on 2 A. I do. 3 carcinogenesis. I want to hear about complications 3 Q. And what rule is that specifically based 4 that might be unique to that product that's not 4 on? 5 part of ordinary urogynecologic practice, so things 5 A. Well, I think if you look at the FDA 6 that don't happen with everyday surgery that maybe 6 Public Health Notifications, the two that were 7 is more specific or unique to that product. Those published, I believe 2008 and 2011, I could be off 8 are the warnings that I'm interested in seeing. 8 on the years, but the FDA specifically gave a 9 9 Q. So is it your opinion that warnings notification to physicians on certain things, so 10 10 don't need to be included in the IFU if doctors those are things that I think are important for us 11 generally know about the risks already? 11 to consider as surgeons in our discussions with 12 12 A. You have to separate what's fundamental patients when gaining informed consent. 13 13 Q. Doctor, I'm going to strike as surgical knowledge with urogynecologic surgery 14 versus what's more product-specific and related to 14 nonresponsive. 15 15 the product. My question is, what rule are you referring 16 Q. Okay. And is that standard for warning 16 to with regard to your requirement as to what's 17 17 based on Dr. Flynn's general requirements or are required in an IFU regarding warnings, not a Public 18 18 Health Notification? you basing that upon some other standard? 19 A. That's based on the standard that was 19 A. Okay. I'm sorry if I missed the 20 20 taught to me as a resident fellow and the standard question. I'm also familiar with the FDA 21 21 that I see used in my practice and the practice recommendations that were put out in the '90s in 22 22 that I participate in with my partners and the the blue book, and they gave some general 23 23 students and residents that we train. So it's not guidelines, some would call them rules, on what 24 my own personal standards. It's the standards that 24 should be included in, you know, medical literature 25 25 the professional societies that I belong to adhere or IFUs. Page 75 Page 77 to, as well as my partners and colleagues around 1 1 Q. That's fine. 2 2 And so is it your testimony today you don't the country. 3 3 know any specific statute or law that mandates what Q. Is that standard based upon some FDA 4 rule? 4 warnings need to be included in an IFU? Is that 5 A. I think that the FDA gives us 5 fair? 6 information and gives us guidelines. I've reviewed 6 A. That's fair. 7 guidelines from the FDA about what they'd like to Q. Is there any internal Ethicon standard 8 8 that you're aware of that sets out what warnings see. 9 9 MR. BENTLEY: I'm going to strike -need to be included in an IFU? 10 A. But they're not rules. 1 0 A. I'm not aware of any internal standards. 11 MR. BENTLEY: So I'm going to strike as 11 I believe they would just adhere to the industry 12 12 nonresponsive. My question is a little different. standards. 13 13 Q. So you don't know that Ethicon has its Q. (By Mr. Bentley) Is your standard that 14 you just discussed based upon some FDA rule? 14 own internal standards that mandate what it has to 15 15 MR. KOOPMANN: Object to form. warn about in labels? 16 16 A. No. I'm not aware of what their internal A. I can speak to standards and guidelines. 17 17 I don't know if that substitutes for rules. standards are. 18 18 Q. (By Mr. Bentley) We don't want you to Q. Would you have liked to have reviewed 19 19 guess. those internal standards in reaching your opinions 20 A. Okay. 20 today in this case regarding the adequacy of 21 Q. Just -- you don't know of any FDA rule 21 Ethicon's warnings regarding its own product? 22 22 that you're assigned to right now that supports or MR. KOOPMANN: Object to form. 23 A. No. 23 that is -- strike that. 24 The general requirement that you just 24 Q. (By Mr. Bentley) You don't care what 25 discussed, do you know if that's based on any 25 Ethicon's internal standards are regarding its

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1	warnings?	1	A. Yes.
2	A. I do care. I think that they're a very	2	Q. And you just told me that you would like
3	reputable company, and I believe that they would	3	to know that there's a risk of damage to the
4	adhere to whatever industry standards are.	4	nerves, to blood vessels or bowel. Is that are
5	Q. So you would expect that Ethicon	5	those risks unique to the Prolift device?
6	followed its own standard in deciding what warnings	6	A. They can be, or they can be part of
7	needed to be included in its IFU for its product	7	ordinary surgery, but you'll see both
8	such as Prolift?	8	possibilities.
9	A. Yeah, the	9	Q. But you would like for those risks to be
10	MR. KOOPMANN: Object to form.	10	included in the label; is that true?
11	A internal and external standards.	11	MR. KOOPMANN: Object to form.
12	Q. (By Mr. Bentley) But you don't know	12	A. I think that those risks that I
13	what those standards are because you haven't	13	mentioned are ones that I've seen in the IFUs for
14	reviewed them?	14	the various products, the Ethicon products that I'm
15	MR. KOOPMANN: Object to form.	15	familiar with.
16	A. No. I don't know. Sorry.	16	Q. (By Mr. Bentley) But are those risks
 17	Q. (By Mr. Bentley) And as you sit here	17	inherent with general surgery other than the
18	today, other than toxicity and carcinogenesis, what	18	Ethicon products?
19	other warnings would you want or expect to be in a	19	A. Yes, they can occur with general
20	Prolift IFU?	20	surgery, native tissue repairs and other
21	A. I think what I mentioned also was unique	21	graft-augmented repairs, sacrocolpopexy.
22	_	22	
23	complications to Prolift that maybe don't occur		Certainly, any surrounding structures can be
	with ordinary urogynecologic surgery.	23	damaged when you're operating near or around them
24	Q. Right. And that's my question. What	24	Q. Right. And you want those risks to be
25	complications do you think based off of that	25	warned of in the Prolift label; is that correct?
	Page 79		Page 81
1	definition or that explanation, what	1	A. Yeah, that's correct.
2	complications you as Dr. Flynn, using your	2	Q. Using your method or your general
3	general requirements that we discussed, what	3	requirements for determining what warnings should
4	warnings, in addition to the toxicity and	4	go into a label, how did you decide that those
5	carcinogenesis, would you want or expect to be in	5	risks that are also inherent with general surgery
6	the label for Prolift?	6	were appropriately put in the IFU for Prolift, as
7	A. I would like some information on	7	you just testified?
8	patients that were contraindicated to the	8	A. I think that what's unique with, say,
9	procedure, so for instance, if the patient's	9	Prolift compared to a native tissue repair is the
10	pregnant, if the patient has bleeding diathesis, if	10	graft material and then the devices that are used
11	the patient has chronic vaginal infection or you	11	to place the graft material, the inserters or
12	know, those are things that, you know, I certainly	12	tunnelers, you know, those devices.
13	would want to be aware of. Other things I'd want	13	Q. I'm sorry. I'm just not understanding,
14	to know about is the risk of mesh exposure or	14	I guess.
15	healing abnormalities, injury or damage to	15	How is it that these risks that you're
16	surrounding structures like the bladder or the	16	discussing that are inherent with general surgery
17	urethra or the bowel, nerves, blood vessels. So I	17	you expect them to be in the Prolift IFU, such as
18	want to know what organs can be injured. I want to	18	potential risk for injury to bowels, to nerves and
19	know what the exposure rate is. I would want to	19	to blood vessels? Why do you think that these
20	know, obviously, if there's any concerns about the	20	general risks of surgery are appropriately put in
21	product causing cancer or causing any untoward side	21	the IFU for Prolift?
22	effects to the patient.	22	A. Because that's what I've seen in other
	-		
23	Q. Doctor, I believe you testified that	23	IFUs that I've reviewed. It seems to me like that
24	you'd want Ethicon to include warnings that were	24	is may be a standard that exists for, say, the TVT
25	unique to the product and the label; is that fair?	25	product or other types of mesh kits.

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1	Q. So your method for deciding whether or	1	analysis of post-market or devices that are
2	not these risks should be included in the IFU is	2	currently on the market, so these are devices that
3	based on what you reviewed in other IFUs; is that	3	are already approved, and they ask the
4	true?	4	manufacturers to prospectively collect data on the
5	A. That's part of it, yes.	5	devices and then to I think they have two years
6	Q. And in addition to that, what else is	6	or so to report to the FDA on what they find.
7	your opinion based upon?	7	Q. So is it your testimony that a 522 order
8	A. It's based upon my own personal	8	requires the manufacturer of a device to perform
9	experience and things that maybe you felt that you	9	additional post-market studies to determine the
10	didn't have a way of knowing based on your current	10	safety of its device?
11	experience or education.	11	A. Yes.
12	Q. Okay. And we've previously discussed	12	Q. And if Ethicon was ordered by the FDA to
13	that you're aware that different doctors have	13	perform 522 studies, does that affect your opinion
14	different experience levels with these mesh	14	in this case?
15	products; isn't that fair?	15	A. No.
16	A. That's correct.	16	Q. Do you know if Ethicon chose to withdraw
17	Q. And so maybe including some	17	the Prolift product from the market instead of
18	complications that you're aware of as more of a	18	doing the 522 studies?
19	specialized expert in your field might be helpful	19	MR. KOOPMANN: Object to form.
20	for some other doctors that aren't as highly	20	A. I don't know what their motivation was.
21	trained; would you agree with that?	21	Q. (By Mr. Bentley) Would you have liked
22	A. Yes.	22	for Ethicon to do additional safety studies?
23	Q. Doctor, prior to writing your report,	23	MR. KOOPMANN: Object to form.
24	did you already hold the opinion that Prolift was	24	A. I would have liked to see Prolift or
25	safe and effective?	25	Prolift+M stay on the market.
			·
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1	A. Yes. I used it for a number of years in	1	Q. (By Mr. Bentley) When the FDA issued
2	my practice, and so I wouldn't have used it for	2	its 522 order to Ethicon regarding its Prolift
3	that many years if I didn't feel it was safe and	3	product, do you know if Ethicon submitted studies
4	effective.	4	that already existed to the FDA in an attempt to
5	Q. Is Prolift currently on the market?	5	get out of having to do additional studies?
6	A. Prolift is no longer on the market.	6	MR. KOOPMANN: Object to form.
7	Q. Do you have an understanding of why	7	A. I'm not aware of what sort of internal
8	Prolift is no longer on the market?	8	strategies they had for dealing with the 522s.
9	A. I have some understanding, but it was a	9	Q. (By Mr. Bentley) Do you know if Ethicon
10	decision that Ethicon made to voluntarily no longer	10	submitted the very studies you're relying upon
11	offer the product.	11	in this report to reach your opinions, do you know
12	Q. Did Ethicon receive a 522 order from the	12	if Ethicon submitted those very studies to the FDA
13	FDA regarding its Prolift product, if you know?	13	to get out of the 522 study requirement?
14	A. I don't know if they did or not, but I	14	A. I don't know.
15	do know that they made that decision voluntarily to	15	MR. KOOPMANN: Object to form.
16	no longer offer the product.	16	Q. (By Mr. Bentley) Assuming that
17	Q. Do you know what a 522 order is?	17	happened, if the FDA then reviewed those studies
18	A. I do.	18	and still determined that Ethicon needed to do
19	Q. Could you tell me?	19	additional studies pursuant to a 522 order, would
20	A. 522 five hundred and twenty-two,	20	that have affected your opinion in this case?
21	five-two-two is a code in the FDA regulatory	21	A. No.
22	system as opposed to, say, 510 or 510(k), so	22	Q. So you don't think it's of any
23	there's different ways the products go through	23	importance that the FDA might have reviewed the
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24 25	regulatory. And the 522 was ordered on mini-slings and transvaginal prolapse kits. The 522 requires	24 25	same studies that you reviewed and determined that the safety and effectiveness of the Prolift has not

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1	been established?	1	A. This is not a systematic review. It's a
2	MR. KOOPMANN: Object to form.	2	report. I think I've testified to that.
3	A. That misstates what I said. I think	3	Q. (By Mr. Bentley) My question: Do you
4	that the FDA has, you know, some goals and some	4	think the FDA is equipped and qualified to do a
5	things that they need to attend to but how I	5	thorough systematic review of the medical
6	prepare my report, was that the question? And the	6	literature regarding Prolift?
7	way I prepared my report was, aside from the 522	7	A. Of course, yes.
8	orders, whether the 522s were ordered or not	8	Q. And so in doing that analysis, if the
9	ordered, I would have prepared the report the same	9	FDA determined that the studies you relied upon in
10	way. It didn't affect how I thought about the	10	this report are not sufficient to establish the
11	product.	11	safety and effectiveness of Prolift, you don't give
12	Q. (By Mr. Bentley) Do you have any	12	that conclusion by the FDA any importance in your
13	understanding of whether or not the FDA employs a	13	report?
14	number of epidemiology experts to review safety	14	MR. KOOPMANN: Object to form; foundation
15	data for products that it's monitoring?	15	A. I wouldn't use the words "any
16	A. I don't know who the FDA has on their	16	importance." It's just one of many pieces of
17	staff. No, I don't.	17	information that I use to formulate my opinion.
18	Q. Would you expect the FDA to have very	18	Q. (By Mr. Bentley) If that had happened,
19	highly trained and skilled professionals to review	19	would that be important for you to review at least?
20	safety data?	20	A. I can't answer that. I mean, we're
21	A. Yes. I know a lot of them are	21	speaking in the hypothetical. I don't believe it's
22	physicians.	22	happened, so I can't answer that one way or
23	Q. And we've already discussed that you	23	another.
24	didn't perform an entire full systematic review of	24	Q. Because you haven't been provided any
25	the literature; isn't that fair?	25	documents demonstrating what Ethicon provided to
	Page 87		Page 89
1	MR. KOOPMANN: Object to form.	1	the FDA; is that fair?
2	A. I don't think that's fair, no.	2	A. That's fair.
3	Q. (By Mr. Bentley) What level of evidence	3	Q. And if, in fact, that had happened and
4	would you consider your report in the sections that	4	you had been provided with those documents showing
5	review the literature on Prolift? Would you	5	that Ethicon provided to the FDA the same studies
6	could you characterize what level of evidence using	6	you relied upon, and the FDA concluded it's not
7	the Oxford Levels of Evidence for me?	7	
8		'	enough to establish safety and effectiveness of
	A. The report has all four levels of	8	Prolift, and they still ordered Ethicon to do 522
9	A. The report has all four levels of evidence. When I get into the sections on the		Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that
	A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review,	8	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that information, would that maybe have affected your
9	A. The report has all four levels of evidence. When I get into the sections on the	8 9	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that
9 10	A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review, you know, and the RCTs, those would be highest levels of evidence. When I talk about my own	8 9 10	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that information, would that maybe have affected your opinion in this report? MR. KOOPMANN: Object to form.
9 10 11	A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review, you know, and the RCTs, those would be highest levels of evidence. When I talk about my own personal experience with the device, my background	8 9 10 11	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that information, would that maybe have affected your opinion in this report?
9 10 11 12	A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review, you know, and the RCTs, those would be highest levels of evidence. When I talk about my own	8 9 10 11 12	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that information, would that maybe have affected your opinion in this report? MR. KOOPMANN: Object to form.
9 10 11 12	A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review, you know, and the RCTs, those would be highest levels of evidence. When I talk about my own personal experience with the device, my background	8 9 10 11 12 13	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that information, would that maybe have affected your opinion in this report? MR. KOOPMANN: Object to form. A. No, I don't think so.
9 10 11 12 13 14	A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review, you know, and the RCTs, those would be highest levels of evidence. When I talk about my own personal experience with the device, my background and maybe some of the pilot studies, that would be	8 9 10 11 12 13	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that information, would that maybe have affected your opinion in this report? MR. KOOPMANN: Object to form. A. No, I don't think so. MR. BENTLEY: Could we take lunch?
9 10 11 12 13 14	A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review, you know, and the RCTs, those would be highest levels of evidence. When I talk about my own personal experience with the device, my background and maybe some of the pilot studies, that would be the lowest levels of evidence. So it's a long	8 9 10 11 12 13 14 15	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that information, would that maybe have affected your opinion in this report? MR. KOOPMANN: Object to form. A. No, I don't think so. MR. BENTLEY: Could we take lunch? MR. KOOPMANN: Sure.
9 10 11 12 13 14 15	A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review, you know, and the RCTs, those would be highest levels of evidence. When I talk about my own personal experience with the device, my background and maybe some of the pilot studies, that would be the lowest levels of evidence. So it's a long report with various levels of evidence.	8 9 10 11 12 13 14 15	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that information, would that maybe have affected your opinion in this report? MR. KOOPMANN: Object to form. A. No, I don't think so. MR. BENTLEY: Could we take lunch? MR. KOOPMANN: Sure. (Recess taken from 1:48 p.m. until
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9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. The report has all four levels of evidence. When I get into the sections on the systematic reviews, such as the Cochrane review, you know, and the RCTs, those would be highest levels of evidence. When I talk about my own personal experience with the device, my background and maybe some of the pilot studies, that would be the lowest levels of evidence. So it's a long report with various levels of evidence. Q. But the section specifically reviewing the medical literature available for Prolift, you wouldn't consider your section reviewing that literature to be a systematic review, right? A. That's correct. Q. Would you think that the FDA would be	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Prolift, and they still ordered Ethicon to do 522 studies if you had been given all that information, would that maybe have affected your opinion in this report? MR. KOOPMANN: Object to form. A. No, I don't think so. MR. BENTLEY: Could we take lunch? MR. KOOPMANN: Sure. (Recess taken from 1:48 p.m. until 2:48 p.m.) Q. (By Mr. Bentley) Doctor, we're back from a short lunch break. Are you ready to go? A. Yes. Q. When you're discussing with your patients whether to use the Prolift implant to

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	Page 90		Page 92
1	risk-benefit discussion.	1	Q. Okay. Do you have an understanding of
2	Q. And you would discuss the potential	2	whether or not Prolift and the polypropylene mesh
3	complications with the procedure with the patient?	3	that Prolift is made of induces a foreign-body
4	A. I would.	4	reaction in the body when implanted?
5	Q. And in your report, it's your opinion	5	A. I have opinions on that, yes.
6	that Prolift has a favorable risk-benefit analysis;	6	Q. Okay. Do you agree that there is a
7	is that correct?	7	foreign-body reaction associated with the
8	A. That's correct.	8	implantation of Prolift in polypropylene meshes to
9	Q. And in reaching that opinion, you	9	treat prolapse?
10	evaluated all the potential risks associated with	10	A. Yes. Any foreign body is going to cause
11	Prolift; is that correct?	11	a foreign-body reaction.
12	A. Correct.	12	Q. Sure. And some foreign bodies might
13	Q. And you balance those against the	13	have a higher degree of foreign-body reaction as
14	potential benefits; is that correct?	14	compared to other foreign bodies; is that fair?
15	A. Yes.	15	A. Yes.
16	Q. And when you're talking about benefits	16	Q. And with a foreign-body reaction, does
17	of the Prolift, is one of the aspects of that	17	the body sometimes create a scar plate as a
18	analysis how Prolift compares in success rates	18	consequence of that process?
19	regarding occurrence as compared to other	19	A. Yes.
20	procedures to treat prolapse?	20	Q. And, in fact, in your practice, have you
21	A. Yes.	21	seen patients have complications from mesh-related
22	Q. And one of the other major alternative	22	implants where the patient has, in fact, suffered
23	procedures to treating prolapse is native tissue	23	from a rigid or hardened scar plate? Is that fair?
24	repair; is that correct?	24	A. Yes.
25	A. Yes.	25	Q. And sometimes you have to remove that
	Page 91		Page 93
1	Q. And it's your opinion that Prolift is	1	hardened scar plate where the body has become
2	significantly more efficacious than a native tissue	2	encapsulated in the mesh and it's become a hard
3	repair; is that correct?	3	scar in the body; is that correct?
4	A. Yes.	4	A. That's correct.
5	Q. And in your report, actually on page 8,	5	Q. And that scar plate process can, in
6	you cite to the 2013 Cochrane review by Maher for	6	fact, lead to other complications, such as pain; is
7	that very proposition; is that correct?	7	that correct?
8	A. Yes.	8	A. I mean, it can lead to a variety of
9	Q. And I think we've previously discussed	9	complications, including pain.
10	you believe that the Cochrane review to be a high	10	Q. And absent that mesh implant, there's
11	level of evidence, according to the Oxford Levels	11	not going to be a foreign-body reaction to a mesh.
12	of Evidence; is that correct?	12	Makes sense, right?
13	A. Yes, that's correct.	13	A. If there's no foreign body, then there
14	Q. When you discuss with your patients the	14	wouldn't be a foreign-body reaction, but there is
15	risk-benefit analysis of Prolift, do you also tell	15	some reaction to surgery, and especially if there's
16	them that you believe that Prolift is more	16	permanent sutures being used.
17	efficacious than native tissue repair?	17	Q. Right. And, of course, the surface area
18	A. I do.	18	of the polypropylene mesh, or the total
19	Q. And when you're discussing the risks	19	polypropylene material used in a Prolift implant is
20	associated with Prolift, do you discuss with your	20	substantially greater than that used or that in
21	patients the potential for Prolift to induce a	21	a suture; is that correct?
22	foreign-body reaction?	22	A. Yes, that's correct.
23	A. I don't use those words specifically. I	23	Q. Do you have any understanding of the
24	talk to them about having postoperative pain or	24	relative size comparison to a Prolene suture versus
25	exposure.	25	how much polypropylene mesh is placed in the body
1 -	on position	1 -	

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	Page 94		Page 96
1	with a Prolift mesh implant?	1	centimeters of Prolift I'm sorry, of Prolene
2	A. I never have seen a comparison. I mean,	2	suture?
3	with the suture-based repair with permanent	3	A. Yes, it's certainly you know, it's 8
4	stitches, it'd probably be anywhere from three to	4	centimeters wide, so it's easily at least 8
5	six sutures being used. You know, the Prolift	5	centimeters.
6	implant is obviously much bigger than that.	6	Q. And that 8 centimeters is comprised of
7	Q. Approximately how long would one of	7	however much Prolene fiber it took to knit together
8	those sutures be where you say that you use	8	to make that implant, right?
9	approximately three to five sutures?	9	A. Yes.
10	A. Well, they're very long, but then you	10	Q. Okay. And assuming that there's a
11	tie them together and you cut the knot. So how	11	foreign-body reaction to the polypropylene suture,
12	long is the knot? Less than a centimeter.	12	would you also expect that there's a foreign-body
13	Q. Okay. And do you have any understanding	13	reaction to the polypropylene that's used in the
14	or appreciation of how much length of polypropylene	14	Prolift mesh implant?
15	goes into making the Prolift mesh that's	15	A. It's the same material, so you'd have a
16	permanently implanted in the woman's body?	16	similar reaction.
17	A. I do.	17	Q. Except for you have a much larger
18	Q. How much is that?	18	quantity of the material in the human body when you
19	A. I believe, going from right to left,	19	implant the Prolift mesh implant as opposed to a
20	it's somewhere around 8 to 10 centimeters.	20	couple of sutures, correct?
21	Q. And that's for the entire implant,	21	A. Correct.
22	correct?	22	Q. And related to that, you would expect
23	A. For the anterior implant.	23	that the foreign-body reaction would be greater
24	Q. Okay. And my question was a little	24	because there's more material for the body to be
25	different.	25	reacting to. Would you agree with that?
	Page 95		Page 97
1	The Prolift implant is actually knitted	1	A. I would agree to that.
2	together using polypropylene-extruded resin; is	2	Q. Okay. In your experience, have you ever
3	that correct?	3	had to remove a hardened scar plate that has
4	A. It uses fibers of the polypropylene,	4	happened as a consequence to the body having a
5	and, yes, it is knitted together.	5	chronic and persistent foreign-body reaction to a
6	Q. Okay. And my question is, do you know	6	suture?
7	or have an understanding of how much fiber, how	7	A. Well, I can't say how it happened, but I
8	much polypropylene fiber goes in that is knitted	8	removed scar plates.
9	together to make the Prolift mesh material?	9	Q. And would the scar plate that's
10	A. In terms of weight?	10	associated with a suture-foreign-body-reaction
11	Q. No, total length.	11	process be substantially smaller than the removed
12	A. Total length? Well, I mentioned you	12	tissue and mesh from a Prolift implant?
13	have 8 centimeters right to left, and I believe	13	A. Yes.
14	it's somewhere around 10 to 15 centimeters anterior	14	Q. So the Prolift revision surgery to take
15	to posterior.	15	out the mesh, including a section of the tissue
16	Q. I apologize. It's probably a bad	16	that's ingrown into it, would be much more invasive
17	question.	17	and much more serious than removing the counterpart
18	But how much do you if you know, do you	18	for a suture; is that correct?
19	have an understanding of what length of	19	A. Yes, that's correct.
20	polypropylene fiber it takes to knit together to	20	Q. Do you discuss that increased risk with
20		21	your patients?
	make the approximately 8-centimeter Prolift		
22	implant?	22	A. I discuss all the complications. I
23	A. I don't know the number.	23	discuss the need for revision surgery and removal.
2.4	O Da wan barra and additional 11 C	1 2 4	I don't think I as into the torus by the time
24 25	Q. Do you have any estimate or idea of whether it's substantially more than a couple	24	I don't think I go into that much detail on how a revision would be done. I tend to focus more on

Page 98 Page 100 1 how the original or initial surgery would be done. 1 Q. Is it true that sometimes, in your 2 2 experience, removing sections of the mesh and Q. Do you think a patient would be 3 3 interested to know what the level of severity is tissue that you decide you can't remove all the 4 associated with treating a complication with the 4 mesh you want in one procedure because it might be 5 Prolift procedure as compared to what level of 5 too invasive? Sometimes you may just do the 6 6 anterior removal portion first; is that correct? revision surgery might be associated with, say, a 7 7 native tissue repair using suture? A. We try to focus on -- you're talking 8 A. I think that's probably more information 8 about a patient that has more than one mesh 9 9 implanted in them? than most patients desire. 10 10 Q. You don't think a patient's concerned Q. Yes. 11 about the level of severity of a revision surgery? 11 A. We try to remove the one that's 12 12 A. No. bothering them the most. And oftentimes it's hard 13 13 to discern where their pain's coming from, but we Q. Does the level of revision -- strike 14 that. 14 tend to try to do the mapping and remove the mesh 15 15 Does the severity of a revision surgery lead that's bothering them in that area. So that'd be 16 to further complications? 16 very unusual if we would remove, say, more than one 17 17 A. Well, any time a surgery is going to mesh in a single operation, yes. 18 take longer or be more invasive, there's going to 18 Q. Do you have an opinion of whether or not mesh contracture or mesh folding can contribute to 19 be increased risks. 19 20 20 a patient suffering from ongoing pain? Q. Approximately what's the size of removal 21 21 when you have to take out a substantial portion of A. I do. 22 22 the Prolift that's been integrated into the body? Q. And what's your opinion? 23 Approximately, in your experience, what's the size 23 A. Well, I think, as it states in the IFU, 24 of the mesh and tissue piece that you take out? 24 that mesh contracture can lead to pain and lead to 25 25 A. Every case is different, but generally having a revision. So there's contracture in Page 99 Page 101 surgery that we consider ordinary, say, up to 20 1 we will take out the part that extruded or exposed. 1 2 2 I use those words interchangeably. And then we percent. Something more than 20 percent, 3 usually will take out a 1- to 2-centimeter rim of 3 especially if it's a 50 percent or 100 percent, 4 mesh that goes beyond the exposed area. 4 then that's going to be more likely to cause pain. 5 O. And if there's not an erosion, but the 5 Q. So you would agree that mesh contracture 6 patient's still suffering from pain, do you 6 can cause pain? 7 sometimes remove a larger section of the tissue and A. I would agree with that, yes. 8 8 mesh? Q. And would you agree that polypropylene 9 9 A. We try to do what's called pain mapping, mesh through the foreign-body reaction process 10 and then we try to focus on where that pain 10 does, in fact, contract? 11 localizes to. And then if we can identify a 11 A. It can contract by a variety of 12 12 problem there, for instance, the scar plate, as you different ways. That's one of them. But I believe 13 mentioned, then that's the area we're going to 13 that it's not so much the mesh that contracts, it's 14 focus on. So every one of these cases is a little 14 the soft tissue around the mesh that contracts. 15 15 bit different depending on what's the indication Q. Through the healing process, through the 16 for revision. 16 foreign-body reaction, is that correct? 17 17 A. Yeah. Q. In your experience, what's been the 18 18 Q. And it's your opinion that that is average, if you can say size of tissue and mesh, 19 19 that you've had to remove when the removal actually warned about in the IFU? 20 procedure is not related to an erosion, when it's 20 A. Yeah, it is warned about in the IFU. 21 21 more related to an ongoing pain complication? Q. And you think, appropriately so, it 22 22 A. I would say somewhere between 3 to 4 should be warned about in the IFU because that is a 23 centimeters. You know, it'd be maybe like a square 23 complication unique to mesh implants? 24 or a rectangle. Three by 4 centimeters would be a 24 MR. KOOPMANN: Object to form. 25 25 pretty extensive dissection. A. You could have contracture with other

	Page 102		Page 104
1	surgeries, but I think that that's something that	1	A. I do.
2	we are concerned about, maybe more concerned about	2	Q. And so the author's essentially saying
3	with mesh.	3	are, Hey, we think native tissue is as efficacious
4	Q. (By Mr. Bentley) Doctor, as we	4	as mesh-related repairs.
5	previously discussed, one of the benefits that you	5	Do you agree with that?
6	believe is associated with Prolift is the fact that	6	A. I agree that that's what the authors are
7	it's more efficacious than native tissue repair; is	7	saying. I don't agree with their conclusion, no.
8	that correct?	8	Q. Okay. And in your report, you don't
9	A. That is correct.	9	discuss this article, right?
10	Q. I'm going to hand you what's being	10	A. Right.
11	marked as Exhibit 3.	11	Q. So there's no way for me to know why you
12	(Exhibit 3 was marked for identification.)	12	disagree with this conclusion; is that fair?
13	Q. And Exhibit 3 is a study by Stanford.	13	A. No, there's no way for you to know.
14	Are you familiar with this study? I'll represent	14	Q. Could you tell me why you think this
15	to you that it's, in fact, on your reliance list,	15	study is not reliable and you don't agree with the
16	but I don't believe it's cited in your report.	16	conclusions?
17	But my question was, are you familiar with	17	MR. KOOPMANN: Object to the form.
18	Stanford's 2012 study?	18	Q. (By Mr. Bentley) Strike that.
19	A. I haven't read this recently. There's	19	Do you think this study is reliable, or have
20	other articles that I'm probably more intimately	20	an opinion one way or the other?
21	familiar with, so	21	A. I don't have an opinion. I'm not that
22	Q. Okay. Using your criteria for	22	familiar with this study.
23	evaluating whether a study has strength	23	Q. But as you said, this is a reliable
24	appropriate strength and weakness, would you	24	journal, correct?
25	consider this to be peer-reviewed literature?	25	A. Correct.
	Page 103		Page 105
1	A. In the National Urogynecology Journal?	1	Q. But you just disagree with the
2	Yes, I'm a reviewer for this journal. I publish in	2	conclusions, correct?
3	this journal. It is peer-reviewed material.	3	A. I cite in my report the meta-analyses
4	Q. It's a respectable journal; is that	4	and the systematic reviews that I rely on, such as
5	correct?	5	the Cochrane review, and the Cochrane review has a
6	A. Yes, it's respectable.	6	contrary result.
7	0.01 1:4 44 1		
	Q. Okay. I just want to draw your	7	
8	Q. Okay. I just want to draw your attention briefly to the abstract. If you turn to	7 8	Q. Okay. So if the Cochrane review had looked at this article and come to the similar
8 9			Q. Okay. So if the Cochrane review had
	attention briefly to the abstract. If you turn to	8	Q. Okay. So if the Cochrane review had looked at this article and come to the similar
9	attention briefly to the abstract. If you turn to the right-hand column about midway through, you can see where it says, "When similar outcome measures	8	Q. Okay. So if the Cochrane review had looked at this article and come to the similar conclusion as Stanford, would that affect your
9 10	attention briefly to the abstract. If you turn to the right-hand column about midway through, you can see where it says, "When similar outcome measures are compared, the published anatomic success rates	8 9 10	Q. Okay. So if the Cochrane review had looked at this article and come to the similar conclusion as Stanford, would that affect your opinion? A. I'm not certain that the Cochrane
9 10 11	attention briefly to the abstract. If you turn to the right-hand column about midway through, you can see where it says, "When similar outcome measures	8 9 10 11	Q. Okay. So if the Cochrane review had looked at this article and come to the similar conclusion as Stanford, would that affect your opinion? A. I'm not certain that the Cochrane review, at least the 2016, didn't look at this.
9 10 11 12	attention briefly to the abstract. If you turn to the right-hand column about midway through, you can see where it says, "When similar outcome measures are compared, the published anatomic success rates of POP," that's pelvic organ prolapse, right?	8 9 10 11 12	Q. Okay. So if the Cochrane review had looked at this article and come to the similar conclusion as Stanford, would that affect your opinion? A. I'm not certain that the Cochrane review, at least the 2016, didn't look at this.
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9 10 11 12 13 14 15 16 17	attention briefly to the abstract. If you turn to the right-hand column about midway through, you can see where it says, "When similar outcome measures are compared, the published anatomic success rates of POP," that's pelvic organ prolapse, right? A. Yeah. I'm sorry, where are you reading? Q. On the second column on the right in the middle of that first paragraph. A. Okay. Q. Do you see where it starts, "when similar outcome measures"? A. I do.	8 9 10 11 12 13 14 15 16 17	Q. Okay. So if the Cochrane review had looked at this article and come to the similar conclusion as Stanford, would that affect your opinion? A. I'm not certain that the Cochrane review, at least the 2016, didn't look at this. The more recent Cochrane review by Maher may have included this. I'd have to go and read all the references in the Cochrane review to see if this was included. Q. But my question is, if the Cochrane review reached a similar conclusion as to what Stanford did in 2012, namely the native tissue
9 10 11 12 13 14 15 16 17 18	attention briefly to the abstract. If you turn to the right-hand column about midway through, you can see where it says, "When similar outcome measures are compared, the published anatomic success rates of POP," that's pelvic organ prolapse, right? A. Yeah. I'm sorry, where are you reading? Q. On the second column on the right in the middle of that first paragraph. A. Okay. Q. Do you see where it starts, "when similar outcome measures"? A. I do. Q. It says, "When similar outcome measures	8 9 10 11 12 13 14 15 16 17 18	Q. Okay. So if the Cochrane review had looked at this article and come to the similar conclusion as Stanford, would that affect your opinion? A. I'm not certain that the Cochrane review, at least the 2016, didn't look at this. The more recent Cochrane review by Maher may have included this. I'd have to go and read all the references in the Cochrane review to see if this was included. Q. But my question is, if the Cochrane review reached a similar conclusion as to what Stanford did in 2012, namely the native tissue repair is as efficacious as mesh-augmented repairs
9 10 11 12 13 14 15 16 17 18 19 20	attention briefly to the abstract. If you turn to the right-hand column about midway through, you can see where it says, "When similar outcome measures are compared, the published anatomic success rates of POP," that's pelvic organ prolapse, right? A. Yeah. I'm sorry, where are you reading? Q. On the second column on the right in the middle of that first paragraph. A. Okay. Q. Do you see where it starts, "when similar outcome measures"? A. I do. Q. It says, "When similar outcome measures are compared, the published anatomic success rates	8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Okay. So if the Cochrane review had looked at this article and come to the similar conclusion as Stanford, would that affect your opinion? A. I'm not certain that the Cochrane review, at least the 2016, didn't look at this. The more recent Cochrane review by Maher may have included this. I'd have to go and read all the references in the Cochrane review to see if this was included. Q. But my question is, if the Cochrane review reached a similar conclusion as to what Stanford did in 2012, namely the native tissue repair is as efficacious as mesh-augmented repairs such as Prolift, would that affect your opinions in
9 10 11 12 13 14 15 16 17 18 19 20 21	attention briefly to the abstract. If you turn to the right-hand column about midway through, you can see where it says, "When similar outcome measures are compared, the published anatomic success rates of POP," that's pelvic organ prolapse, right? A. Yeah. I'm sorry, where are you reading? Q. On the second column on the right in the middle of that first paragraph. A. Okay. Q. Do you see where it starts, "when similar outcome measures"? A. I do. Q. It says, "When similar outcome measures are compared, the published anatomic success rates of POP," or pelvic organ prolapse, "of anterior and	8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Okay. So if the Cochrane review had looked at this article and come to the similar conclusion as Stanford, would that affect your opinion? A. I'm not certain that the Cochrane review, at least the 2016, didn't look at this. The more recent Cochrane review by Maher may have included this. I'd have to go and read all the references in the Cochrane review to see if this was included. Q. But my question is, if the Cochrane review reached a similar conclusion as to what Stanford did in 2012, namely the native tissue repair is as efficacious as mesh-augmented repairs
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	Page 106		Page 108
1	Q. (By Mr. Bentley) Doctor, have you	1	(Exhibit 4 was marked for identification.)
2	testified today extensively that you relied upon	2	Q. And I think that Iglesia, again, is on
3	the Cochrane review?	3	your list materials but not cited in your report.
4	A. Yes, I have.	4	My question is, are you familiar with the
5	Q. And if the Cochrane review changed their	5	Iglesia study?
6	conclusion, that would not affect your opinion in	6	A. Yes, I am.
7	this case?	7	Q. And is this from a respectable journal?
8	A. I would have to read that report and see	8	A. Yes, it is.
9	why they changed their opinions. I seriously doubt	9	Q. Do you know of any problems offhand with
10	they're going to change their opinion based on one	10	this study?
11	article.	11	A. I do.
12	Q. Sure. If they happened to, say, change	12	Q. What are those problems?
13	their opinion based on more articles, would that	13	A. I think the experience of Dr. Iglesia in
14	further affect your opinion in this case?	14	terms of her ability to do a mesh-augmented repair
15	A. I mean, if there's a greater level of	15	has been called into serious question by a number
16	evidence, then you're going to consider that more	16	of people. She's a very experienced native-tissue
17	heavily.	17	surgeon, a very inexperienced mesh surgeon. So I
18	Q. As you sit here, can you give me any	18	think if you take someone that's done thousands of
19	reason as to why you discount the strength of this	19	native tissue repairs and compare the results with
20	study?	20	the first ten or twenty Prolift kits that they've
21	A. It's not so much that I discount the	21	done, the results are not going to be the same as
22	strength of this, it's that I rely more heavily on	22	what other more experienced mesh implanters would
23	other systematic reviews that are larger that	23	
24	included a greater number of studies.	24	report. Q. And Doctor, does that cut both ways,
25	-	25	that an experienced surgeon with extensive
23	Q. You rely more heavily on studies that	23	that an experienced surgeon with extensive
	Page 107		Page 109
1	support your opinion; is that correct?	1	experience in native tissue repair might be more
2	MR. KOOPMANN: Object to form.	2	successful at using native tissue repair as opposed
3	A. That works both directions. The studies	3	to less-experienced surgeons with native tissue
4	that I rely on formulate my opinions. Those two	4	repair?
5	things are interchangeable.	5	A. Yes. I think we get good at the
6	Q. (By Mr. Bentley) Right. But you don't	6	operations that we do commonly and that we're
7	present any argument or analysis as to why you	7	comfortable with.
8	think that this study by Stanford is any less	8	Q. And as we discussed, there are certain
9	credible than the studies that you rely upon that	9	complications associated with a mesh-based repair
10	happen to support your opinion; is that fair?	10	that are not inherent in a native tissue repair; is
11	A. Let's see. This is just one study. I'd	11	that true?
12	be interested to see other studies like this, but I	12	A. Yeah, there's a few.
13	feel comfortable with the studies I've relied on.	13	Q. And looking at the Iglesia study under
14	MR. BENTLEY: Okay. I'm going to strike	14	the abstract on the first-page results, it states,
15	that as nonresponsive.	15	"Sixty-five women were recruited from January 200"
16	Q. (By Mr. Bentley) My question, Doctor,	16	to August 2009, when the study was halted due to
17	you don't present any argument or analysis as to	17	predetermined stopping criteria for vaginal mesh
18	why you think this study by Stanford is any less	18	erosion at a median follow-up of 9.7 months."
19	credible than the studies that you rely upon that	19	My question is, does that concern you, that
20	happen to support your opinion; is that fair?	20	this study was halted for meeting a for
21	MR. KOOPMANN: Object to form.	21	exceeding the threshold for erosions?
22	A. That's fair.	22	
			A. It does concern me that they were having
23	Q. (By Mr. Bentley) I'm going to hand you	23	more complications than what others had reported.
24	what's being marked as Exhibit 4, which is a study	24	Q. And then in the "Conclusion" section
25	by Iglesia.	25	there, it says, "At 3 months, there is a high

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	Page 110		Page 112
1	vaginal mesh erosion rate (15.6%) with no	1	study.
2	difference in overall objective and subjective cure	2	Q. And if you'll turn your attention,
3	rates." And you disagree with that statement	3	please, to the "Conclusion" section in the
4	strike that.	4	abstract, the authors conclude, the "Rate of
5	"At 3 months, there's a high vaginal mesh	5	complications requiring reoperation and the total
6	erosion rate (3.6%) with no difference in overall	6	reoperation rate was highest for vaginal mesh kits
7	objective and subjective cure rates."	7	despite a lower reoperation rate for prolapse
8	My question is, that doesn't agree with your	8	recurrence and shorter overall follow-up"; do you
9	opinions in this case, does it?	9	see that, Doctor?
10	MR. KOOPMANN: Object to form.	10	A. Yes.
11	A. I used primarily the systematic reviews	11	Q. And does that conclusion affect your
12	and Cochrane reviews to formulate my opinions, and	12	opinions in this case?
13	this is of a lower level of evidence, and it	13	A. No.
14	doesn't affect my opinions.	14	Q. Does that conclusion support or
15	MR. BENTLEY: And I'm going to strike that	15	contradict your conclusions in this case?
16	as nonresponsive.	16	A. My report doesn't have conclusions. My
17	Q. (By Mr. Bentley) My question was, the	17	report is a number or a series of opinions that
18	conclusions reached in this study are contrary to	18	I've offered. I don't think it's a, like, a paper
19	your opinions in this report, correct?	19	or a manuscript where I got introduction methods
20	MR. KOOPMANN: Object to form.	20	results and conclusions. It's not written that
21	A. It's contrary to some of my opinions.	21	way.
22	Q. (By Mr. Bentley) And nowhere in your	22	Q. Okay. Thank you.
23	report do you discuss the weaknesses of this study;	23	In your report, you state one of your
24	is that true?	24	opinions is that Prolift is more efficacious than
25	A. That's true.	25	native tissue repair; is that correct?
23	A. That's true.		native tissue repair, is that correct:
	Page 111		Page 113
1	Q. And nowhere in your report do you	1	A. That's correct.
2	discuss the criticisms you have of Dr. Iglesia's	2	Q. And by efficacious, I mean that there
3	ability to use a mesh-based implant; is that true?	3	would be less recurrence of the prolapse with the
4	A. Not in this report, but I did I have	4	Prolift prolapse repair kit as compared to a native
5	discussed that in other places, other people have,	5	tissue repair; is that correct?
6	yes.	6	A. That's correct.
7	Q. Did you discuss that anywhere in your	7	Q. Okay. And the conclusion here from
8	Prolift+M report?	8	these authors is stating that there's actually a
9	A. No.	9	higher reoperation rate with the vaginal mesh kits
10	Q. Do you disclose that opinion of	10	as compared to other surgical procedures; is that
11	Dr. Iglesia's surgical ability anywhere in any of	11	correct?
12	your reports in the mesh litigations involving	12	A. That's correct.
13	Ethicon?	13	Q. And so my question is, this conclusion
14	A. No.	14	is actually contrary to your opinions reached in
15	Q. I'm going to hand you what's being	15	your report; isn't that correct?
	moderal on Delethite E. And this is a study by	16	A. That's correct.
16	marked as Exhibit 5. And this is a study by	- "	
16 17	Dr. Diwadkar, dated 2009, from Obstetrics and	17	Q. And in your report, do you discuss any
17	• •		Q. And in your report, do you discuss any reason as to why this study is any less credible
17 18	Dr. Diwadkar, dated 2009, from Obstetrics and	17	
17 18	Dr. Diwadkar, dated 2009, from Obstetrics and Gynecology.	17 18	reason as to why this study is any less credible
17 18 19	Dr. Diwadkar, dated 2009, from Obstetrics and Gynecology. (Exhibit 5 was marked for identification.)	17 18 19	reason as to why this study is any less credible than the other studies that you cite to in support
17 18 19 20	Dr. Diwadkar, dated 2009, from Obstetrics and Gynecology. (Exhibit 5 was marked for identification.) Q. And I believe this is another study that	17 18 19 20	reason as to why this study is any less credible than the other studies that you cite to in support of your opinion?
17 18 19 20 21	Dr. Diwadkar, dated 2009, from Obstetrics and Gynecology. (Exhibit 5 was marked for identification.) Q. And I believe this is another study that is, in fact, on your reliance materials but, again, not cited in your report.	17 18 19 20 21	reason as to why this study is any less credible than the other studies that you cite to in support of your opinion? A. No.
17 18 19 20 21	Dr. Diwadkar, dated 2009, from Obstetrics and Gynecology. (Exhibit 5 was marked for identification.) Q. And I believe this is another study that is, in fact, on your reliance materials but, again,	17 18 19 20 21 22	reason as to why this study is any less credible than the other studies that you cite to in support of your opinion? A. No. Q. As you sit here today, do you have any

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	Page 114		Page 116
1	He's already reviewed it. If you want to go off	1	A. That's fair.
2	the record, I'm happy to	2	Q. Doctor, would you be critical of Ethicon
3	MR. KOOPMANN: If you want to ask him	3	if they had warned of this increased risk in the
4	specific questions about a document, then I	4	IFU?
5	think	5	A. I don't have any criticisms for Ethicon
6	MR. BENTLEY: My question was	6	in regards to the IFU.
7	MR. KOOPMANN: you ought to read it on	7	MR. BENTLEY: I'm going to move to strike as
8	the record.	8	nonresponsive.
9	Q. (By Mr. Bentley) As you sit here today,	9	Q. (By Mr. Bentley) My question, Doctor,
10	Doctor, do you have any understanding or	10	is, would you have been critical of Ethicon if they
11	appreciation of a reason why this study is any less	11	had chosen to warn of this increased risk of
12	credible than the other studies cited in your	12	reoperation in the Prolift IFU? Would you have
13	report in support of your opinion?	13	been critical of Ethicon for including that
14	A. I'd have to go off the record and review	14	information in the IFU?
15	the article, but as I sit here right now, I'm not	15	A. I'm not I wouldn't be critical, no,
16	that familiar with the article, so I can't	16	they no.
17	criticize the article because I'm not familiar with	17	Q. Would it be helpful for some doctors
18	it.	18	that weren't aware of this article to know that
19	Q. But the article does reach a conclusion	19	information when they were doing an informed
20	that's contrary to your opinion, right?	20	consent with their patients?
21	MR. KOOPMANN: Object to form; asked and	21	MR. KOOPMANN: Object to form.
22	answered.	22	A. I don't think it'd be helpful.
23	A. Yeah, the conclusion here says that the	23	Q. (By Mr. Bentley) You don't think it'd
24	rate of complications requiring reoperation was	24	be helpful for some doctors to know there's a
25	higher.	25	higher risk of reoperation with Prolift-based
23	ingiter.	23	nigher risk of reoperation with Fronti-based
	Page 115		Page 117
1	Q. (By Mr. Bentley) Do you think patients	1	repairs as compared to other surgical procedures?
2	would like to know that when they're deciding	2	A. I think I've already answered that
3	whether or not to undergo a surgical implant of the	3	question, but I think, again, you have to go
4	Prolift device?	4	through the risks and benefits of the procedure.
5	A. Patients want to know what the risks and	5	What I discuss with patients is that the benefit of
6	benefits of the procedure are. That's what we	6	the graft-augmented repair is, in my opinion and
7	discuss with them every day when we do our informed	7	that of many others in the systematic reviews like
8	consents.	8	the Cochrane review, is that you get a better
9	Q. So is that a yes to my question, Doctor?	9	subjective and objective cure rate. There is a
10	MR. KOOPMANN: Object to form.	10	higher risk of graft exposure when you're using a
11	A. Patients want to know risks, you know,	11	graft, whether it's mesh or a biological. You're
12	so you have to gather that from as much information	12	going to have potential for healing abnormalities.
13	as you can collect. There's no way you can be	13	I discuss that with patients, yes.
14	aware of every single article in the medical	14	MR. BENTLEY: I'm going to strike as
15	literature.	15	nonresponsive, Doctor.
16	Q. (By Mr. Bentley) But this article is	16	Q. (By Mr. Bentley) My question,
17	actually on your reliance list, so presumably you	17	specifically, though, is, the information based in
18	are aware of it, correct?	18	this study that indicates that there's a higher
19	A. I am, but some articles I'm more	19	reoperation rate with Prolift-based repairs, do you
20	familiar with than others.	20	think that would have been helpful for doctors to
21	Q. And my question was, simply, patients	21	
			know to inform their patients during the
22	would want to know that there may be a higher	22	risk-benefit discussion so they can get informed
23	reoperation rate with Prolift mesh as opposed to	23	consent as to the procedure to implant a Prolift
24	other surgical techniques to treat prolapse; is that fair?	24	device? MR. KOOPMANN: Object to form.

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	Page 118		Page 120
1	A. No, I don't think this article would	1	Q. And if you'll turn to the fifth page,
2	have been helpful to them.	2	you can see the "Clinical Implications" section.
3	MR. KOOPMANN: Can we go off the record for	3	Are you with me? It'll be the last page. And
4	a second?	4	under "Clinical Implications" on the last page, it
5	(Discussion held off the record.)	5	states, "Transvaginal mesh plates with prolapse
6	Q. (By Mr. Bentley) Doctor, is the risk of	6	kits can lead to debilitating complications such as
7	reoperation a serious risk for patients?	7	chronic pain, dyspareunia, symptomatic mesh
8	A. Serious risk?	8	erosion, and vesicovaginal fistula that may require
9	Q. Yeah, that was a bad question. Sorry.	9	extensive mesh excision"; did I read that
10	Are there risks inherent with any surgery?	10	correctly?
11	A. Yes.	11	A. Yes.
12	Q. And so having an additional surgery	12	Q. And would you agree that those are
13	presents additional risks; is that correct?	13	potential complications with using transvaginal
14	A. Having a reoperation?	14	mesh-based repair kits such as Prolift? Would you
15	Q. Sure.	15	agree with that statement?
16	A. Yes.	16	A. Yes.
17	Q. And likewise, not having a reoperation	17	Q. And the second clinical implication is,
18	is probably safer than having a second surgery.	18	"Surgeons who place transvaginal mesh using
19	Would you agree with that?	19	prolapse kits may be unaware of complications
20	A. It would depend on the particular	20	because most patients seek care from a different
21	disease. Some people need a reoperation. If they	21	physician"; did I read that correctly?
22	don't, then their health made be, you know, more in	22	A. Yes.
23	harm than not having the reoperation. You have to	23	Q. And I believe you've testified,
24	look at each patient individually.	24	actually, that you treat complications from other
25	Q. Right. And we're here discussing	25	surgeons who have implanted products; is that
			surgeons who have implanted products, is that
	Page 119		Page 121
1	Prolift and prolapse, which, I'm sure you're aware,	1	correct?
2	having a second surgery in the pelvis to treat	2	A. Yes.
3	recurrence of prolapse is that a good idea or a	3	Q. And so sometimes maybe the other doctor
4	bad idea, generally?	4	might not know about the complication; is that
5	A. Having a second surgery to reoperate for	5	correct?
6	prolapse?	6	A. A small percentage. I would say most of
7	Q. Yeah.	7	the time the referrals I receive from other doctors
8	MR. KOOPMANN: Object to form.	8	are from the implanting surgeon.
9	A. That's something we generally try to	9	Q. Okay. So do you agree or disagree with
10	avoid. That's what we're trying to do here by	10	this second clinical implication that we just
11	using a graft-augmented repair.	11	reviewed, that sometimes surgeons may not know that
12	Q. (By Mr. Bentley) And the study that we	12	their patient had complications?
13	just looked at showed that there's a higher risk of	13	A. Well, sure, there might be a few
14	reoperation using the mesh-based repair kit, right?	14	patients here or there that you might not be aware
15	A. In this study, yes.	15	of, but I think the overwhelming majority of
16	Q. Doctor, I'm going to hand you what's	16	patients and surgeons are still connected.
17	being marked as Exhibit 6. And this is an article	17	Q. Right. And so this leads to the reason
1 - /		1	of why you probably want to warn about things in
18	by Dr. Ridgeway in the American Journal of	18	or why you productly want to warn about things in
	by Dr. Ridgeway in the American Journal of Obstetrics and Gynecology.	18	the IFU so everyone can have full knowledge. Would
18			
18 19	Obstetrics and Gynecology.	19	the IFU so everyone can have full knowledge. Would
18 19 20	Obstetrics and Gynecology. (Exhibit 6 was marked for identification.)	19 20	the IFU so everyone can have full knowledge. Would you agree with that?
18 19 20 21	Obstetrics and Gynecology. (Exhibit 6 was marked for identification.) Q. And this is, again, on your reliance	19 20 21	the IFU so everyone can have full knowledge. Would you agree with that? MR. KOOPMANN: Object to form.
18 19 20 21 22	Obstetrics and Gynecology. (Exhibit 6 was marked for identification.) Q. And this is, again, on your reliance materials and not cited in your report.	19 20 21 22	the IFU so everyone can have full knowledge. Would you agree with that? MR. KOOPMANN: Object to form. A. I think the IFU is adequate, and I think

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	Page 122		Page 124
1	Q. (By Mr. Bentley) My question was,	1	the FDA approves IFUs?
2	because of this clinical implication that some	2	A. I know they require an IFU. I don't
3	surgeons don't know about their complications,	3	know how much it goes beyond that to say if this
4	would you agree that it's reasonable to include the	4	was adequate or written properly.
5	complications associated with Prolift in the IFU so	5	Q. And you don't know if there's some law
6	that all the doctors have all the information	6	or regulation prohibiting Ethicon from, say, adding
7	available to them? Would you agree with me that	7	risk rates to the IFU to better inform doctors and
8	that's reasonable?	8	thereby facilitate the informed consent process?
9	MR. KOOPMANN: Object to form.	9	A. I'm not aware of, one way or the other.
10	A. No, I don't I don't agree with the	10	Q. Would you be critical if Ethicon added
11	statement.	11	more information to the IFU such as maybe
12	Q. (By Mr. Bentley) So you don't think	12	complication rates?
13	it's a good idea to put all of the complications	13	MR. KOOPMANN: Object to form.
14	associated with Prolift in the IFU?	14	A. I don't have an opinion on that either
15	A. I think that the complications that are	15	way.
16	stated in the IFU are adequate. I think there's	16	Q. (By Mr. Bentley) Would that have been
17	enough information on complication data there.	17	helpful for some doctor, do you think?
18	Q. Do you know if the IFU cites any	18	A. Not necessarily.
19	specific data?	19	Q. Why don't you think it'd be helpful?
20	A. Does it cite specific data? It lists,	20	A. I don't think a lot of physicians read
21	it itemizes potential risks, but IFUs are not	21	the IFU. And with that said, I think people rely
22	heavily referenced.	22	more on their education, their training, what
23	Q. So there's no specific data citing the	23	they've learned from colleagues and courses, so I
24	IFU?	24	think the IFU's one of many things they rely on,
25	A. I'd have to look at the Prolift IFU to	25	but I don't think it's the top of the list.
	The full mayor to rook at the Fronte II of to		out I don't timik it's the top of the list.
	Page 123		Page 125
1	be certain, but I'm not aware of major references	1	Q. Do you in your personal practice review
2	in the IFU. In the Prolift monograph, certainly	2	the IFU?
3	there's plenty of references of complications and	3	A. I do.
4	information that surgeons should be aware of.	4	Q. How frequently do you do that?
5	MR. BENTLEY: I'm going to strike after	5	A. I do that on all new products that I
6	"references in the IFU."	6	use. And if there's a change to the IFU, then I
7	Q. (By Mr. Bentley) Doctor, are you aware	7	would re-review it.
8	of any regulation or law that prohibits Ethicon	8	Q. How do you become aware if there's a
9	from adding evidence or data to the IFU?	9	change to the IFU?
10	A. Each time evidence is added to the IFU,	10	A. Various ways. It might be reported to
11	my understanding is that the IFU then has to go	11	me by some representative from that manufacturer.
12	back through the regulatory and get approved again.	12	I may get a written correspondence or an e-mail
13	So it's not an easy process to add or subtract	13	Q. So unless
14	things from an IFU.	14	A or it might be some personal
15	Q. It's your testimony today that the IFU	15	communication between me and one of the
16	gets approved by the FDA?	16	representatives.
17	A. Maybe "approved" is not the right word,	17	Q. So is it your testimony today that you
18	but it's reviewed, you know, by regulatory	18	review an IFU when you're encountering new product
19	agencies. The IFU is a public document.	19	or when some representative from the company tells
20	Q. Does the FDA have authority to force a	20	you there's been a change? Is that your testimony?
21	medical device manufacturer such as Ethicon to	21	A. That's my testimony.
22	change their IFU?	22	Q. Doctor, do you believe that there's been
23	MR. KOOPMANN: Object to form.	23	an evolution in understanding of the complications
24	A. I don't know the answer to that.	24	associated with polypropylene prolapse repair kits
25	Q. (By Mr. Bentley) And you don't know if	25	such as Prolift?
1 '	() Sendey) Time you don't know it		

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	Page 126		Page 128
1	A. I do.	1	Ultrapro data from hernia surgery, and so it was
2	Q. And what do you think the evolution has	2	something that many surgeons were attracted to. We
3	shown?	3	tried it. I did about a hundred of each, and then
4	A. I think it's an evolving material	4	the Pro product was no longer being offered, but at
5	science. There's new information that's discovered	5	least, when preparing this Prolift and Prolift+M
6	and looked at and reviewed.	6	report, my review of the literature, my own
7	Q. And has the science shown that maybe	7	personal experience is I didn't see a clinical
8	larger pore, lighter weight mesh is associated with	8	significant difference between how the two products
9	reduced complications?	9	performed in terms of efficacy or safety.
10	A. The data's very mixed.	10	Q. So do you think there's better data
11	Q. Do you have any understanding as to what	11	associated with Prolift versus Prolift+M?
12	the purpose for or what the purpose was of	12	A. There's certainly Prolift is a much
13	Prolift+M?	13	more widely studied product. There was a greater
14	A. The goal of Prolift+M was to leave less	14	number of articles to review and systematic
15	foreign body behind in the patient.	15	reviews.
16	Q. And that has a clinical that has	16	Q. So taking that into account, and taking
17	clinical significance to you, correct?	17	into account your testimony that there's no benefit
18	A. Potential.	18	to Prolift+M, why would you use Prolift+M today if
19	Q. Okay. And what's the potential clinical	19	it was still available?
20	significance of leaving less foreign body mesh	20	A. I don't think that was my testimony. My
21	material in the body?	21	testimony was I think I would use either product,
22	A. The idea of having less foreign body	22	Prolift or Prolift+M, if either of them was still
23	would be less foreign-body reaction, and that there	23	available, because they were equivalent products.
24	would be less pain or exposure associated with the	24	So there are patients that I feel would be ideal
25	device.	25	for either of those products.
	Page 127		Page 129
1	Q. And from your experience, do you think	1	Q. If there's no benefit to Prolift+M, how
2	that that is, in fact, true?	2	can you decide if a patient's ideal for Prolift or
3	A. No, it's not true. In my experience, it	3	Prolift+M?
4	was something that seemed very intuitive, but the	4	A. What I mentioned is I would be pleased
5	literature has not shown that.	5	with either product. They're both good products.
6	Q. So you don't think there is any benefit	6	They were equivalent, according to the literature
7	to using Prolift+M that left less mesh and foreign	7	and according to my own personal experience, so I'm
8	body in the patient's body?	8	not saying I favor +M over Prolift. If you ask the
9	A. The systematic reviews and the	9	question in reverse, I would be just as pleased to
10	retrospective studies don't show that, so the	10	have used Prolift, you know, last week or you
11	complication rate between Prolift+M and Prolift	11	know, compared to +M.
12	were not significantly different.	12	Q. Even though Prolift had more data
13	Q. So there's no benefit to using Prolift+M	13	available?
14	as opposed to Prolift?	14	A. Prolift had more data, but I think there
15	A. I don't see any benefit.	15	was enough data available on +M, and I had enough
16	Q. Okay. But in your practice, you	16	personal experience with +M, to feel that it was at
17	switched away from using Prolift to Prolift+M; is	17	least performing equally.
18	that correct?	18	Q. Doctor, do you think that mesh
19	A. That's correct.	19	contracture is a clinically significant
	Q. I'm just not understanding. So why	20	complication for the patient?
20			
20	would you switch to a new product if there's no	21	A. It would depend on the degree of
	would you switch to a new product if there's no benefit?	21 22	contracture.
21	would you switch to a new product if there's no benefit? A. As I mentioned earlier, I'm an early		Q. Can mesh contracture be a clinically
21 22	would you switch to a new product if there's no benefit?	22	contracture.

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	Page 130		Page 132
1	Q. And that could lead to maybe revision	1	A. Well, there would be a variety of ways.
2	surgery where you have to remove part of the mesh?	2	The first thing we'd start off with is vaginal
3	A. Correct.	3	estrogen to try to soften the vaginal mucosa to
4	Q. Do you have an understanding of how mesh	4	make it more supple.
5	contracture leads to pain for a patient?	5	Second treatment would be pelvic floor
6	A. I think that the theories there's a	6	massage or physical therapy to try to reduce the
7	number of theories that have been proposed, one of	7	muscle from being under tension. Oftentimes it's
8	which is that the contracture can lead to, you	8	really just tension, not contracture; it's hard to
9	know, an exaggerated foreign-body response. And so	9	separate those two things, and they can happen
10	if someone has a sensation that they have a foreign	10	independent of each other.
11	body in them, then that's going to cause pain.	11	And then if the nonoperative management
12	Q. It's your testimony that a foreign-body	12	doesn't work, then one can consider revision
13	response is essentially what the pain is that a	13	surgery.
14	patient's experiencing?	14	Q. Is it your testimony that treatment with
15	A. No, I mentioned that you asked me	15	estrogen cream can improve mesh contracture where
16	if how contracture can cause pain.	16	there's not an erosion present?
17	Q. Right.	17	A. "Mesh contraction" may be too specific
18	A. And I said that's one of the factors.	18	of a term. It's hard to separate. When I see a
19	Contracture can cause pain by eliciting a	19	patient that has a mesh implant regardless of an
20	foreign-body response.	20	exposure or no exposure that has pain, if the
21	Q. Is there any other way that you know of	21	mucosa feels thin over the graft material, then
22	that contracture can cause pain?	22	we're going to prescribe vaginal estrogen.
23	A. Yes.	23	Q. Can estrogen cream treat a hardened scar
24	Q. How is that?	24	plate?
25	A. Well, the scar plating that was	25	A. No.
	The won, the soul planing that was		11. 110.
	Page 131		Page 133
1	mentioned earlier in the deposition. The scar	1	Q. When there's no erosion present but a
2	plating can lead to a stiff area in the vagina that	2	patient's still suffering from pain, can estrogen
3	can cause pain. It could also place soft tissue	3	cream treat that pain?
4	under tension, and soft tissue under tension can	4	A. It can treat vaginal atrophy and
5	cause pain.	5	dryness. That may be contributing to the pain.
6	Q. Could it also entrap nerves, for	6	Most of the pain is multi-factorial.
7	example?	7	Q. Isn't it true that usually you have to
8	A. I'm not aware of that. There may be	8	treat those types of complications with surgical
9	some potential for it, but I have not seen that	9	intervention?
10	clinically personally, or seen that in the	10	A. No, that's not how I would describe it.
11	literature.	11	Q. In your experience, Doctor, have you
12	Q. Can mesh contracture also lead to	12	seen situations where the mesh can become infected?
13	dyspareunia?	13	A. Have I seen infected mesh?
14	A. Yes.	14	Q. Yes.
15	Q. Can mesh contracture also lead to	15	A. Yes.
16	painful intercourse for a woman's partner?	16	Q. And, in fact, do you have a theory that
17	A. Yes.	17	infection leads to pain?
18	Q. And mesh contracture can lead to	18	A. I think it's one of many theories, but
19	shortening of the vaginal canal?	19	yeah.
20	A. Yes.	20	Q. Do you not hold that theory anymore?
21	Q. In your experience, how would you treat	21	A. No, I do hold that theory. It's a
22	a patient suffering from the serious complications	22	theory that others have proposed. I've read that
23	we discussed associated with mesh contracture? In	23	in the medical literature.
24	your experience, how would you approach treating	24	Q. Is there some reason why you don't
25	that patient?	25	discuss that potential complication in your report
" "	mat patient:	"	arseass that potential complication in your report

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	Page 134		Page 136
1	in this case?	1	My question is, why don't you discuss your
2	A. I believe I discussed it in my TVT	2	own article discussing these very issues in your
3	report, but I don't see that I discussed it here in	3	report?
4	the Prolift report.	4	A. This article here was an overview of the
5	Q. Do you think that the theory that mesh	5	controversy of incontinence and prolapse surgery,
6	infection leads to pain is applicable to the	6	so this article was in response to the FDA Public
7	Prolift implant?	7	Health Notification. And I was solicited by the
8	A. Yes, I do.	8	American Urologic Association to write this article
9	Q. Do you think that would be important for	9	to help urologists understand what was in the FDA
10	patients to know that's a potential complication?	10	PHN. So that's why this was written. This is
11	A. That's a complication we discuss with	11	something that I didn't rely on for this Prolift
12	patients with every surgery we do, the risk of	12	report because this is not specific to Prolift.
13	infections.	13	Q. The title of the article is, "The Use of
14	Q. You discuss the potential for	14	Surgical Mesh for Incontinence and Prolapse
15	infection-related pain with your patients?	15	Surgery: Indications for Use, Technical
16	A. I mention to them any time I place a	16	Considerations and Management of Complications"; is
17	foreign body, that the foreign body can potentially	17	that correct?
18	become infected, whether that's silicone or	18	A. That's correct.
19	polypropylene, whatever the implant is.	19	Q. And Prolift is a surgical mesh kit
20	Q. And do you discuss that you have a	20	that's used for treatment of prolapse, correct?
21	theory that the infection leads to pain?	21	A. Correct.
22	A. I discuss with them the consequences of	22	Q. So this article deals with the very
23	infection, pain being one of them, mesh revision	23	issues that you discuss in this report; isn't that
24	being another one, so it's one of many reasons why	24	correct?
25	one would revise an implant.	25	A. That's correct.
	Page 135		Page 137
1	Q. Do you think that's information that	1	Q. Do you stand by your words in this
2	would have been helpful to be in the IFU?	2	article that you're a co-author of?
3	MR. KOOPMANN: Object to form.	3	A. I do, but again, this is similar to the
4	A. I believe it's in the IFU. I think	4	Urology Times article. The AUA updates are a lower
5	infection is discussed in the IFU.	5	level of evidence. They reflect my opinions. This
6	Q. (By Mr. Bentley) Is the clinical	6	is not a peer-reviewed publication. The AUA update
7	significance of infection which causes pain in the	7	series is not something that's published. It's
8	IFU?	8	available to members of the American Urologic
9	A. Now you're connecting a lot of thoughts	9	Association.
10	there, so I don't think it's written in that	10	Q. Right. But you stand by your words in
11	manner, but I think it's reasonable knowledge that	11	this article, right?
12	most surgeons would understand, that infection can	12	A. Yes, I do.
13	cause pain.	13	Q. If you could please turn to Bates number
14	Q. Would you have been critical of Ethicon	14	0764, or on the article, it says page 133.
15	for putting that information in the IFU?	15	A. Okay.
16	A. No, I wouldn't have been critical.	16	Q. On the left-hand column, talking about
17	Q. Doctor, I'm going to hand you what's	17	complications, about halfway down, it says "Vaginal
1	Q. Doctor, I'm going to hand you what's		
18	being marked as Exhibit 7.	18	Wall Extrusion," and then in bold you write,
		18 19	
18	being marked as Exhibit 7. (Exhibit 7 was marked for identification.)		"Vaginal wall extrusion occurs more commonly with a
18 19	being marked as Exhibit 7. (Exhibit 7 was marked for identification.) Q. And there is a paper by Terlecki and	19	
18 19 20	being marked as Exhibit 7. (Exhibit 7 was marked for identification.) Q. And there is a paper by Terlecki and yourself published in the AUA Update Series '10.	19 20	"Vaginal wall extrusion occurs more commonly with a reinforced synthetic repair than a biological
18 19 20 21	being marked as Exhibit 7. (Exhibit 7 was marked for identification.) Q. And there is a paper by Terlecki and	19 20 21	"Vaginal wall extrusion occurs more commonly with a reinforced synthetic repair than a biological repair"; did I read that correctly?
18 19 20 21 22	being marked as Exhibit 7. (Exhibit 7 was marked for identification.) Q. And there is a paper by Terlecki and yourself published in the AUA Update Series '10. I'm sure you're familiar with this presumably	19 20 21 22	"Vaginal wall extrusion occurs more commonly with a reinforced synthetic repair than a biological repair"; did I read that correctly? A. Yes.

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	Page 138		Page 140
1	Q. That's what the evidence shows; isn't	1	surgeon would understand someone who has
2	that correct?	2	immunosuppression, diabetes, smoking, these are
3	A. That's correct.	3	risk factors for healing abnormalities. They're
4	Q. And do you discuss that with your	4	not unique to polypropylene mesh. And so I believe
5	patients?	5	a reasonable surgeon would understand these risk
6	A. I do.	6	factors.
7	Q. And do you think Ethicon should have	7	MR. BENTLEY: I'm going to move to strike as
8	warned about that in the IFU?	8	nonresponsive.
9	MR. KOOPMANN: Object to form.	9	Q. (By Mr. Bentley) Doctor, my question
10	A. Are you asking me if Ethicon should have	10	was, simply, do you think that this information
11	compared and contrasted their products to other	11	would have been helpful for doctors to have in the
12	people's products in their IFU?	12	IFU?
13	Q. (By Mr. Bentley) Well, if you know and	13	MR. KOOPMANN: Object to form.
14	Ethicon was aware that there's a higher risk of	14	A. No, I don't. I don't believe it would
15	erosion with Prolift as compared to other repairs,	15	be helpful.
16	do you think that would have been helpful	16	Q. (By Mr. Bentley) Going down to the next
17	information to include in the IFU?	17	paragraph, in bold, you continue, "Any adverse mesh
18	MR. KOOPMANN: Object to form.	18	implantation features that can be mitigated
19	A. I don't believe that's the purpose of	19	preoperatively should be addressed before stress
20	the IFU, so no.	20	urinary incontinence or pelvic organ prolapse
21	Q. (By Mr. Bentley) Remind me. What's	21	surgery." Do you agree with that?
22	your idea of what the purpose of the IFU is.	22	A. I do.
23	MR. KOOPMANN: Object to form.	23	Q. Do you think it would have been helpful
24	· ·	24	for Ethicon to tell doctors how they can mitigate
25	A. The purpose of the IFU is to make a	25	
23	reasonable surgeon aware of unique complications,	25	complications preoperatively?
	Page 139		Page 141
1	and maybe more common complications, describe	1	A. No, I don't think that was Ethicon's
2	organs that can be injured, the things that we	2	responsibility.
3	mentioned earlier in the deposition. And I believe	3	Q. You don't think it's Ethicon's
4	mesh extrusion is listed in the IFU, so I believe	4	responsibility to inform doctors how to decrease
5	that's adequate.	5	potential complications and increase the efficacy
6	Q. (By Mr. Bentley) Okay. On the next	6	of the products that it sells to be permanently
7	column over, middle of the page, bolded, it says,	7	implanted in women's bodies?
8	"Patient factors that may lead to an increased risk	8	MR. KOOPMANN: Object to form.
9	for extrusion include age, estrogen status, prior	9	A. I think it's the job of the professional
10	radiation, active vaginal infection, smoking,	10	medical societies and the responsibility of the
11	obesity, immunosuppression, diabetes and	11	physician to be educated properly on basic
12	concomitant hysterectomy"; did I read that correct?	12	fundamental surgical knowledge.
13	A. Correct.	13	Q. (By Mr. Bentley) So you don't think
14	Q. And do you still hold that opinion?	14	Ethicon should share information it's aware of
15	A. I do.	15	regarding how to decrease complications or increase
16	Q. Do you know if that information's	16	efficacy of its products?
17	conveyed in the IFU for doctors?	17	MR. KOOPMANN: Object to form.
18	A. I don't believe so.	18	A. No, I think the information would have
19	Q. Do you think it would have been helpful	19	been redundant.
20	for doctors to know that there are certain patient	20	MR. BENTLEY: Move to strike after "No."
21	_	21	
	factors that may affect the risk for extrusion?		Q. (By Mr. Bentley) Further down on the
22	MR. KOOPMANN: Object to form.	22	page under "Urinary tract erosion," it states
23	A. These factors that are listed are	23	strike that.
24	factors that would affect any wound healing, and so	24	Future down the page under "Urinary tract
25	this is common knowledge. I think any reasonable	25	erosion," you state, "A rare but dreaded

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	Page 142		Page 144
1	complication of graft-based stress urinary	1	Q. Is that a yes?
2	incontinence and pelvic organ prolapse surgery is	2	A. Yes.
3	erosion into the bladder, urethra or rectum. The	3	Q. On the next page, Doctor, the bottom is
4	complication can occur regardless of graft	4	135, in the column on the right, the second bolded
5	composition but is certainly more common with	5	sentence says, "We have noticed an escalation in
6	synthetic material"; did I read that correctly?	6	the severity of such complications and have had to
7	A. Yes, you read that correctly.	7	adopt an increasingly complex and aggressive
8	Q. Do you still hold that opinion?	8	approach to these healing abnormalities. Our
9	A. I do.	9	salvage protocol is designed to manage complex
10	Q. Do you know if that's included in the	10	graft complications and prevent the need for a
11	IFU?	11	reoperation"; did I read that correctly?
12	MR. KOOPMANN: Object to form.	12	A. Yes.
13	A. I think that it warns about risks to	13	Q. And does that refer to what we discussed
14	surrounding structures, including bladder, urethra	14	earlier about the escalation of understanding of
15	and the rectum, and so it mentions about	15	the complications associated with mesh-based
16	perforation of visceral structures, et cetera, so	16	repairs for prolapse?
17	yes, I think it's mentioned in the IFU.	17	A. I don't believe we've discussed
18	Q. (By Mr. Bentley) Does the IFU convey	18	escalation earlier.
19	the severity of that complication as you state in	19	Q. Has there been an escalation in the
20	your paper?	20	severity of such complications, as you state here
21	A. No, that's not the role of the IFU.	21	in this paper?
22	Q. Turning to the next page, on the right	22	A. It's hard to say. I certainly have seen
23	column towards the bottom of the page under	23	a number of complications in my practice. I don't
24	"Complications unique to mesh kits," you state, in	24	know if that is reflective of the referral nature
25	bold, the second sentence, "Disadvantages of a kit	25	of my practice, being in one location for a longer
			of my practice, being in one focution for a longer
	Page 143		Page 145
1	include the expense, blind needle passage,	1	time. It's hard to say. But, you know, we saw an
2	unfamiliarity of procedure steps, and potential for	2	increase in the number of complications. That's
3	marketing to inexperienced pelvic surgeons who may	3	something that I've reported on up until around
4	overestimate the usefulness of the kit"; did I read	4	2011, 2012 when we began to see a plateau. And we
5	that correctly?	5	continue to see that plateau. So the number of
6	A. Yes.	6	complications that I've been managing for the last
7	Q. Do you still hold that opinion?	7	four to five years has been relatively stable.
8	A. I do.	8	Q. And Doctor, my question is, Doctor, in
9	Q. In your report, have you explained how	9	your report, do you discuss your statement here
10	that opinion affects the risk-benefit profile of	10	that you've seen an increase or an escalation in
11	the Prolift product?	11	the severity of such complications? Do you discuss
12	A. I'm not certain what you're asking me	12	that in your report?
13	there.	13	A. No.
14	Q. That was probably a bad question.	14	Q. Is there any reason why you didn't
15	In your report, do you discuss this opinion	15	discuss your observation that there's been an
16	discussing the disadvantages of a mesh kit that are	16	increase or an escalation in the severity of
17	unique to the mesh kit? Do you discuss all of	17	mesh-related complications in your report?
18	those complications in your report?	18	A. As I mentioned earlier, the report is
	A. I don't believe I discuss expense in the	19	specific to Prolift and Prolift+M. It's not
19	TINGS STATE OF THE PARTY OF THE	20	specific to management of transvaginal mesh
20	report. Unfamiliarity of procedure steps, I don't		
	report. Unfamiliarity of procedure steps, I don't itemize all those, no.	21	complications.
20		21 22	complications. Q. You don't think that management of
20 21	itemize all those, no.		
20 21 22	itemize all those, no. Q. Would those complications associated	22	Q. You don't think that management of

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	Page 146		Page 148
1	that's the focus of the report.	1	A. I was aware of the complications. I
2	Q. You don't think the severity of	2	think the choice of the word "escalation" was a
3	complications in the attendant revision surgery	3	poor choice of words, really, on my part.
4	affects the risk-benefit profile of the Prolift or	4	Q. In the next sentence, you talk about
5	Prolift+M medical device?	5	your salvage protocol.
6	A. I believe I've discussed the	6	Do you discuss your salvage protocol with
7	risk-benefit profile in the report.	7	patients when you're giving an informed consent as
8	Q. But in I'm sorry. Go ahead.	8	to whether to implant a meshed-based repair?
9	A. So I'm comfortable with what I have	9	A. No. As I mentioned earlier, I focus on
10	reported here. I have an entire section	10	the implant surgery and the risks and benefits of
11	overviewing complication prevention and management.	11	that surgery. I don't talk about subsequent
12	If you look on page 30, "Complication Prevention	12	surgeries.
13	Management," so I feel that this report is adequate	13	Q. So in your discussion of risks, you
14	and comprehensive. There's a section on safety of	14	don't think it's relevant to discuss that you have
15	the product. That includes three to four pages on	15	to use a mesh strike that.
16	safety. The clinical data summary on page 32 has a	16	In your discussion of the risks in doing
17	table that I cut and paste from the Prolift	17	informed consent with a patient, you don't think
18	monograph, including information on various	18	it's relevant to discuss the severity of the
19	complications, the total of the complications, the	19	revision surgery that you've termed a "salvage
20	number of patients in these studies. So I believe	20	protocol"? You don't think that's relevant in the
21	that this report is quite adequate in commenting on	21	risk-benefit discussion?
22	complications.	22	MR. KOOPMANN: Object to form; compound,
23	Q. My question wasn't in any way about the	23	asked and answered.
24	adequacy of your report.	24	A. I don't think it's a benefit. And I
25	My question was, simply, do you feel that	25	didn't come up with the term "salvage protocol."
	Page 147		Page 149
1	this statement, your words from your 2010 paper	1	Q. (By Mr. Bentley) But this is your
2	that you've seen an escalation in the severity of	2	paper, right?
3	mesh-related complications, does that affect the	3	A. It is, but the word "salvage" you'll see
4	risk-benefit profile of the Prolift mesh implant to	4	repeatedly in the medical literature. Dr. Jerry
5	treat prolapse?	5	Blaivas uses that word. A number of people use
6	A. No, I don't believe so.	6	that word when describing the use of the
7	Q. You don't think the severity of	7	pubovaginal sling. Some people use the word
8	complications affects the risk-benefit profile of a	8	"terminal procedure." It has a lot of words that
9	medical device?	9	are attached to it, but "salvage" is not a word
10	A. That's a complex statement, but I think	10	that I came up with.
11	that what I mentioned earlier is that I believe	11	Q. But it's bolded in your paper, right?
12	that that escalation that I was witnessing was just	12	A. It's bolded in my paper.
13	reflective of the referral network that I had	13	Q. Okay. On the next page, Doctor, if you
14	developed, so these complications were being	14	could look at the left-hand column of page 136, the
15	referred to me. And in retrospect, I think that	15	second bolded section, you state, "However,
16	was what was happening. I don't think the	16	dyspareunia and pelvic pain can occur in complete
17	complications were happening more commonly, or the	17	absence of extrusion, erosion or infection. In
18	incidence or prevalence was changing in any way, it	18	these cases, it is thought to be due to tension on
19	was just where the patients were being referred to	19	the graft, graft contracture, superficial graft
20	and the willingness of physicians in the local	20	placement or nerve injury."
21	community to manage these patients.	21	Do you still hold that opinion, Doctor?
22	Q. So it's your testimony that you weren't	22	A. Yes, that's the opinion I just stated
23	aware of the escalation and severity of mesh	23	earlier in regards to graft contracture and
24	complications until you happened to be referred	24	tension, and muscle under tension, et cetera.
25	some patients in your personal clinical practice?	25	Q. And those are indeed complications that

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1	can happen with the Prolift or Prolift+M implant;	1	benefits, so there's quite a bit in those sections.
2	isn't that correct?	2	And I think that those sections outline the
3	A. Correct.	3	potential foreign-body response.
4	Q. Yet, in your report, the only unique	4	Q. Your summary in your paper on your
5	complication I believe you discuss is mesh	5	summary in Exhibit 7, your 2010 paper, towards the
6	exposure.	6	end of that paragraph in bold, you state,
7	Is there any reason why you don't detail	7	"Therefore, reinforced pelvic floor repairs should
8	these other complications in your report as unique	8	only be performed in well-selected patients after
9	complications to the Prolift or Prolift+M?	9	they provide informed consent." Does that apply to
10	A. I believe I discuss more than that in	10	Prolift implants? Is Prolift a mesh-based pelvic
11	the report.	11	floor repair?
12	Q. Okay. Turn to page 26 of your Prolift	12	A. This report was written in 2010, so it
13	report discussing the IFU. In that first paragraph	13	would apply to patients going forward that would
14	under Section A, you have a sentence that states,	14	have a reinforced repair after the FDA Public
15	the IFU, "It warns of the only unique complication	15	Health Notification and after, you know, ten or so
16	with the device," and you have a dash, and it says,	16	years of experience with pelvic floor kits.
17	"mesh exposure"; do you see that?	17	Q. So you think Prolift or Prolift+M would
18	A. I do.	18	still be appropriate in carefully selected
19	Q. Is there any reason why you didn't	19	patients?
20	discuss the other complications we just reviewed in	20	A. In carefully selected patients, yes.
21	your paper from 2010 in your report in this case?	21	Q. Do you think the IFU should have maybe
22	A. Well, because I was trying to separate	22	conveyed that information that Prolift is only
23	complications that are unique to the graft versus	23	appropriate in well-selected patients?
24	complications that occur with ordinary	24	MR. KOOPMANN: Object to form.
25	urogynecologic surgery. So if you do a native	25	A. When the IFU was written, I think it did
	D 171		D 170
	Page 151		Page 153
1	tissue repair, you can end up with contracture in	1	a good job at the time in detailing the risks and
2	the vagina. You could end up with muscle under	2	benefits. No one really knew at the time who the
3	tension, superficial sutures. Certainly you can	3	right who was the perfect, you know, correct
4	entrap the nerve when doing procedures like	4	patient, properly selected patient or that
5	sacrospinous ligament fixation. So again, I'm just	5	well-selected patient.
6	trying to separate the what's unique to the	6	Q. (By Mr. Bentley) But as more
7	graft material versus what's not unique.	7	information was collected and as you came to know
8	Q. Is there a unique foreign-body response	8	more about which patients this was more appropriate
9	profile to the polypropylene mesh used in Prolift	9	for, that information should have been conveyed in
10	as compared to native tissue repair?	10	the IFU; isn't that correct?
11	A. Yes.	11	MR. KOOPMANN: Object to form.
12	Q. And you don't discuss that in your	12	A. No, that's not correct.
13	report; isn't that correct?	13	Q. (By Mr. Bentley) You don't think it's
14	A. I think mesh exposure can happen by	14	helpful for Ethicon to tell doctors which patients
15	foreign-body response. Mesh exposure can occur by	15	are appropriate for implantation of its medical
16	a variety of different mechanisms, but that's one	16	devices?
17	of them.	17	MR. KOOPMANN: Object to form.
18	Q. And you don't discuss that in your	18	A. I don't think that's Ethicon's
19	report, isn't that correct, the unique foreign-body	19	responsibility. I think it's the responsibility of
	response to polypropylene or Prolift-based prolapse	20	professional medical societies and the
20		21	responsibility of the individual.
21	repair?		
21 22	A. I'm not certain if I used the word	22	Q. (By Mr. Bentley) Do you think that it's
21 22 23	A. I'm not certain if I used the word "unique," but I believe there's an entire section	22	Ethicon's responsibility to inform physicians how
21 22	A. I'm not certain if I used the word	22	

	Page 154		Page 156
1	A. I think it's to inform them how to	1	that suggested that?
2	safely use their products. That goes back to the	2	A. I'm not reading that. Were you reading
3	IFU. I think the IFU is one of many mechanisms	3	the first sentence?
4	that are used to inform patients and physicians	4	Q. The second paragraph, "A careful review
5	I'm sorry, to inform physicians on the product, but	5	of publications looking at success for anterior
6	it's not the only the only piece of information.	6	colporrhaphy reveals that for many years, the
7	Q. (By Mr. Bentley) And that wasn't my	7	reported primary outcome for successful treatment
8	question.	8	was the correction of stress urinary incontinence";
9	My question is, do you think that it's	9	did I read that correctly?
10	Ethicon's responsibility to inform physicians how	10	A. Yes.
11	to safely use its products?	11	Q. Okay. And were you aware that many of
12	A. Yes.	12	the studies discussing the success of native tissue
13	Q. And if Ethicon had some information that	13	were actually looking at whether the prolapse
14	it knew would help physicians use its products more	14	successfully treated for a correction of SUI?
15	safely, Ethicon should have shared that information	15	A. Yes, the Kelly plication, for instance,
16	with those physicians, correct?	16	· -
17	MR. KOOPMANN: Object to form.	17	was a repair that was done for stress urinary incontinence.
18	A. I believe they did share the	18	
19	information, as much information as they had. It's	19	Q. Were you aware I'm sorry. Go ahead.A. Yes, so I was aware of that, yes.
20	•	20	•
21	reflected in the Prolift monograph and other	21	Q. Were you aware that that would have reduced the overall success rate attributed to
22	efforts that they made to share information with	22	
23	the physicians. Q. (By Mr. Bentley) And is it your	23	native tissue repair for recurrence of prolapse as opposed to prolapse and stress urinary
24	testimony that all the information shared in the	24	incontinence?
25	monograph is also in the IFU?	25	A. I am aware that some of that was
23	monograph is also in the fr 0:	23	A. I am aware that some of that was
	Page 155		Page 157
1	A. No, the monograph is a much longer	1	included. How it affected it, I don't I'd have
2	document. It's a supplement to the IFU.	_	
1	**	2	to review each article to see if it had lower
3	MR. BENTLEY: Can we take a short break?	3	outcomes and pull the average down.
4	MR. BENTLEY: Can we take a short break? MR. KOOPMANN: Sure.	3 4	outcomes and pull the average down. Q. Okay. And you haven't performed that
	MR. BENTLEY: Can we take a short break? MR. KOOPMANN: Sure. (Recess taken from 4:07 p.m. until	3	outcomes and pull the average down. Q. Okay. And you haven't performed that analysis, right?
4	MR. BENTLEY: Can we take a short break? MR. KOOPMANN: Sure. (Recess taken from 4:07 p.m. until 4:21 p.m.)	3 4 5	outcomes and pull the average down. Q. Okay. And you haven't performed that analysis, right? A. I have not.
4 5	MR. BENTLEY: Can we take a short break? MR. KOOPMANN: Sure. (Recess taken from 4:07 p.m. until 4:21 p.m.) Q. (By Mr. Bentley) Doctor, we're back	3 4 5	outcomes and pull the average down. Q. Okay. And you haven't performed that analysis, right? A. I have not. Q. If you turn to page 25, the
4 5 6	MR. BENTLEY: Can we take a short break? MR. KOOPMANN: Sure. (Recess taken from 4:07 p.m. until 4:21 p.m.) Q. (By Mr. Bentley) Doctor, we're back from a short break. Are you ready?	3 4 5	outcomes and pull the average down. Q. Okay. And you haven't performed that analysis, right? A. I have not. Q. If you turn to page 25, the "Conclusions" section, under the first paragraph
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MR. BENTLEY: Can we take a short break? MR. KOOPMANN: Sure. (Recess taken from 4:07 p.m. until 4:21 p.m.) Q. (By Mr. Bentley) Doctor, we're back from a short break. Are you ready? A. Yes. Q. If you could please turn back to what we marked as Exhibit 3, it was a Stanford study from 2012. And if you could turn to page 24. The page number's in the top left corner. A. Yes. Q. On page 24, on the right-hand column, there's a section titled "Anterior compartment"; do you see that on the right-hand column? A. Yes. Q. The second paragraph starts, "A careful review of publications looking at success for anterior colporrhaphy reveals that for many years,	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	outcomes and pull the average down. Q. Okay. And you haven't performed that analysis, right? A. I have not. Q. If you turn to page 25, the "Conclusions" section, under the first paragraph under "Conclusions," the last sentence states, "The overall success rates of native tissue and mesh augmentation repairs when recurrent prolapse is the primary outcome measure are very similar"; did I read that correctly? A. Yes. Q. And do you have an opinion as to whether or not that statement is correct? A. I do. Q. And what's your opinion? A. That it's not correct. Q. But you haven't performed the reanalysis that you just previously testified that you would
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. BENTLEY: Can we take a short break? MR. KOOPMANN: Sure. (Recess taken from 4:07 p.m. until 4:21 p.m.) Q. (By Mr. Bentley) Doctor, we're back from a short break. Are you ready? A. Yes. Q. If you could please turn back to what we marked as Exhibit 3, it was a Stanford study from 2012. And if you could turn to page 24. The page number's in the top left corner. A. Yes. Q. On page 24, on the right-hand column, there's a section titled "Anterior compartment"; do you see that on the right-hand column? A. Yes. Q. The second paragraph starts, "A careful review of publications looking at success for anterior colporrhaphy reveals that for many years, the reported primary outcome for successful	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	outcomes and pull the average down. Q. Okay. And you haven't performed that analysis, right? A. I have not. Q. If you turn to page 25, the "Conclusions" section, under the first paragraph under "Conclusions," the last sentence states, "The overall success rates of native tissue and mesh augmentation repairs when recurrent prolapse is the primary outcome measure are very similar"; did I read that correctly? A. Yes. Q. And do you have an opinion as to whether or not that statement is correct? A. I do. Q. And what's your opinion? A. That it's not correct. Q. But you haven't performed the reanalysis that you just previously testified that you would need to do to know whether or not these statements
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. BENTLEY: Can we take a short break? MR. KOOPMANN: Sure. (Recess taken from 4:07 p.m. until 4:21 p.m.) Q. (By Mr. Bentley) Doctor, we're back from a short break. Are you ready? A. Yes. Q. If you could please turn back to what we marked as Exhibit 3, it was a Stanford study from 2012. And if you could turn to page 24. The page number's in the top left corner. A. Yes. Q. On page 24, on the right-hand column, there's a section titled "Anterior compartment"; do you see that on the right-hand column? A. Yes. Q. The second paragraph starts, "A careful review of publications looking at success for anterior colporrhaphy reveals that for many years, the reported primary outcome for successful	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	outcomes and pull the average down. Q. Okay. And you haven't performed that analysis, right? A. I have not. Q. If you turn to page 25, the "Conclusions" section, under the first paragraph under "Conclusions," the last sentence states, "The overall success rates of native tissue and mesh augmentation repairs when recurrent prolapse is the primary outcome measure are very similar"; did I read that correctly? A. Yes. Q. And do you have an opinion as to whether or not that statement is correct? A. I do. Q. And what's your opinion? A. That it's not correct. Q. But you haven't performed the reanalysis that you just previously testified that you would need to do to know whether or not these statements

Page 158 Page 160 1 reviews. Those reviews adjust for these sort of 1 page numbers, so it would be the second-to-last 2 variables. That's the strength of systematic 2 page of Exhibit 8 that we're looking at. 3 3 reviews. So it can adjust for these minor details. A. Where there's some pictures? 4 Q. Okay. And if you turn the page, please, 4 O. Yes. 5 to page 26, at the top, the second sentence states, 5 A. Mm-hmm. 6 "One recent prospective randomized study reported 6 Q. In that first paragraph on the left-hand 7 no difference in the mesh augmentation and native column, in the bold, they state, "They compared the 8 tissue groups, but the study was stopped early due 8 initial length of the implanted mesh and 9 9 to a high incidence of mesh erosion/exposure sonographically measured mesh length 6 weeks 10 10 (15%)." And that refers to footnote 78. If you'll postoperatively, observing a decrease in the mesh 11 turn to footnotes, you'll see that footnote 78 is, 11 length of 60%"; do you see that? 12 12 in fact, the Iglesia study that we previously A. I do. 13 13 looked at; is that correct? Q. And this is from, actually, the creators 14 14 A. That's correct. of the Prolift product; is that correct? 15 15 Q. And so that's another study showing A. Well, I don't know the other authors 16 that, in fact, native tissue repair is similarly 16 besides Jacquetin. 17 17 efficacious as mesh-augmented repair; is that Q. Okay. If you would turn to the second 18 18 correct? page of the article, on the left-hand column, the 19 A. We've already been through that study. 19 first full paragraph starts, "Between 2000 and 2005 20 20 Q. Right. Doctor, I'm going to hand you our team participated in the development of the 21 21 what's being marked as Exhibit 8. tension-free vaginal mesh technique. Over time it 22 22 (Exhibit 8 was marked for identification.) appeared that mesh retraction was probably a 23 23 O. And this is a study from a number of contributing factor to recurrence, postoperative 24 people. The first author is Velemir. And I 24 pain and dyspareunia"; do you see that? 25 25 believe this is also on your reliance list and not A. I do. Page 159 Page 161 discussed in your report. Q. And do you think that it's of importance 1 1 2 2 My question is, are you familiar with this that the creators of this technique are actually 3 3 study? reporting on mesh contracture leading to these 4 A. I have some familiarity with this study. 4 complications? Is that important to you? 5 I'm familiar with the work of Dr. Jacquetin. I 5 A. Well, yeah, it is important to me. 6 believe he did a lot of the original Prolift 6 Q. And is it important to you that these 7 7 studies. authors are reporting that they're observing up to 8 8 60 percent mesh contracture with the Prolift Q. He was, in fact, part of the original 9 9 French TVM group that came up with the Prolift technique that they came up with? 10 device; is that correct? 10 A. I don't know if they're using the word 11 A. I believe he was part of that group, 11 "contracture." They talk about a decrease in mesh 12 12 along with Dr. Clave and others. length of 60 percent anterior meshes. It just says 13 13 "decrease in length." They don't say how that Q. Okay. And Dr. Clave's published on 14 foreign-body reaction to the mesh; is that correct? 14 happened. 15 15 Q. Is that important to you, Doctor? A. That's correct. 16 16 A. A decrease in length? Q. And what level of mesh contracture would 17 17 need to exist for you to determine that it's Q. Right. 18 18 clinically significant, approximately? A. Yes, that's important. 19 19 A. What I've seen reported in various Q. And that's above your 20 percent 20 articles is 20 percent or more. 20 threshold; is that correct? 21 Q. 20 percent or more of mesh contracture 21 A. That's correct. 22 22 would lead to clinically significant outcomes; is Q. And do you think that it would be 23 that correct? 23 important for doctors to know that the inventors of 24 A. Potentially, yes. 24 the Prolift technique who observe mesh shrinkage or 25 25 Q. If you could turn to page -- I don't see contracture of up to 60 percent of the overall

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	Page 162		Page 164
1	length would that be important for doctors to	1	patients very difficult, very time-consuming, very
2	know?	2	challenging in many ways. I think the emphasis
3	A. Yes.	3	from industry was starting to change towards
4	Q. Would that maybe affect the informed	4	sacrocolpopexy and other procedures, so as I
5	consent process when discussing risks and benefits	5	mentioned earlier in the deposition, that I've
6	of this product?	6	continually evolved and adopted new procedures.
7	A. No.	7	And the robotic-assisted laparoscopic
8	Q. Doctor, do you know when Prolift and	8	sacrocolpopexy with Y meshes were really what was
9	Prolift+M were pulled from the market?	9	starting to come into favor at the time.
10	A. I don't believe they were ever pulled	10	Q. So I guess I don't understand. How is
11	from the market. I believe that Ethicon stopped	11	it that you would still today be using these
12	offering the product sometime around 2012.	12	products if you have continued to evolve and use
13	Q. And you've testified that if these	13	newer products? Which is it, Doctor?
14	products were still on the market, you'd still be	14	A. Well, as I mentioned earlier in the
15	implanting them today; isn't that correct?	15	deposition, I might evolve to have my primary
16	A. That's correct. That's what I stated in	16	procedure or my preferred procedure, but I still
17	my report.	17	like to have a lot of options as a surgeon, and so
18	Q. What products are you currently using	18	it's rare that I ever stop or discontinue doing
19	today to treat prolapse?	19	another procedure altogether. So I perform
20	A. I perform native tissue repairs, as I	20	graph-augmented repairs, sacrocolpopexy and native
21	always have. I continue to perform transvaginal	21	tissue repairs. I've done that for the 15 years
22	graft-augmented repairs, but I use biological	22	I've been in practice. And so I've been very
23	material to do that, and with permanent sutures	23	consistent in what I do.
24	using the Capio device. And then I perform	24	There are patients that I see that are not
25	sacrocolpopexy using polypropylene mesh.	25	appropriate for sacrocolpopexy. They've failed
	Page 163		Page 165
1	Q. Did you use polypropylene-mesh-based	1	native tissue. They've failed graft-augmented
2	kits such as Prolift and Prolift+M up until the	2	repair with biologicals, and they would be good
3	time that they were discontinued by Ethicon?	3	candidates for a Prolift or a Prolift+M.
4	A. I don't remember the exact date, but	4	Q. That's a very specific patient profile;
5	close to it, yes. I believe my last case was	5	isn't that right?
6	sometime in February of 2012, and I think in July	6	A. That's one of many patients I see in my
7	of 2012 was when Prolift and Prolift+M were no	7	
8		8	practice, yes. Q. But that specific profile you just
9	longer being offered, so there was a five-month difference.	9	described, you still consider Prolift would be an
10			
	Q. Why did you stop using these products	10	appropriate option for that patient, or Prolift+M; is that correct?
11	five months prior to them being discontinued?	11	
12	A. For the most part, it was based on	12	A. That's correct.
13	changing practice patterns.	13	Q. Would you agree that other surgical
14	Q. So your report states that you would	14	techniques are more appropriate for a first-line
15	still continue to be using these products today if	15	treatment of prolapse as opposed to Prolift or
16	they were available, correct?	16	Prolift+M?
17	A. Correct.	17	MR. KOOPMANN: Object to form.
18	Q. But prior to their discontinuation, you	18	A. Primary versus recurrent is just one of
19	changed your practice pattern such that you quit	19	the many factors. I look at other factors like the
20	using them; is that correct?	20	patient's tissue quality, the stage of prolapse,
21	A. Not that I quit. I started using other	21	the POPQ store, what their risk-benefit tolerance
22	procedures. It was a very contentious time after	22	is. So it's one of many factors that goes into the
23	the FDA Public Health Notification. It created a	23	decision-making of whether or not I'm going to do
24	lot of controversy in the media and amongst	24	native tissue on a primary repair or
25	patients, and so it made the conversations with	25	graft-augmented on the primary repair.
		1	

		Z ,	
	Page 166		Page 168
1	Q. (By Mr. Bentley) And using a	1	information in the IFU, to have the appropriate
2	graft-augmented repair, is it correct to state that	2	patient profile described in the IFU if that
3	you wouldn't necessarily use a polypropylene-based	3	information's available?
4	mesh kit such as Prolift or Prolift+M on every	4	A. No, it's not helpful. It goes well
5	patient that came to you? You might look at other	5	beyond the scope of the IFU.
6	grafts as being more appropriate for that first	6	Q. Are you aware of any law or regulation
7	prolapse surgery; is that correct?	7	that states that the scope is limited such that you
8	A. Yeah, I've never looked at it that way.	8	can't include patient profile information in the
9	I've always offered a variety of procedures based	9	IFU?
10	on the indications.	10	A. There's no law, but I believe the
11	Q. Do you feel that other graft-based	11	standard is to just put what's essential.
12	repairs are efficacious for some patients that	12	Q. Essential to using the product safely,
13	present with prolapse for a first-line treatment	13	is that correct?
14	surgical option?	14	A. That's correct, and helping physicians
15	A. Yeah, there's certainly a number of	15	identify the product.
16	patients that I treat with graph augmentation	16	Q. Are there other patient factors that
17	primarily.	17	make Prolift or Prolift+M more appropriate for one
18	Q. Do you feel that that strike that.	18	patient as opposed to a biological graft?
19	Do you know if the IFU warns strike that.	19	A. Yeah, there's a long list of factors
20	Do you know if the IFU indicates that	20	that we use in the decision-making.
21	Prolift should only be used for select patients,	21	(Exhibit 9 was marked for identification.)
22	like you've just described, as a first-line	22	Q. I'm going to hand you what's being
23	surgical treatment for prolapse?	23	marked as Exhibit 9. And this is an e-mail from
24	A. The IFU does not it's not intended to	24	yourself to Jonathan Fernandez, dated December
25		25	•
23	guide surgeons on which patients they should	25	19th, 2011. Do you see that?
	Page 167		Page 169
1	select. That's up to the surgeon and the patient.	1	A. I do.
2	Q. And similarly, you don't know if the IFU	2	Q. Do you recall sending this e-mail to
3	guides strike that.	3	Jonathan Fernandez?
4	Similarly, the IFU doesn't guide surgeons as	4	A. I don't.
5	to whether or not Prolift+M and other	5	Q. Up at the top there, that's your e-mail
6	polypropylene-based prolapse mesh kits is	6	address; isn't that correct?
7	appropriate for first-line surgical treatment of	7	A. That's correct.
8	prolapse. The IFU doesn't state that; is that	8	Q. Do you have any reason to doubt that you
9	correct?	9	sent this e-mail in 2011?
10	A. That's correct.	10	A. I don't.
11	Q. Would you have been critical if Ethicon	11	Q. And in the body of the e-mail, you
12	shared that information with the IFU surgeons?	12	begin, "Jon, All is well with me, although my
13	A. No, I wouldn't have been critical.	13	practice is really changing from mesh kits to
14	Q. Generally, it's advantageous to provide	14	Biologicals, ASC and spending time trying to help
15	information regarding the patient profile that's	15	J&J in a class action vs. Prolift PS"; did I read
16	appropriate for a surgical option in the IFU.	16	that correctly?
17	Would you agree that that's helpful and appropriate	17	(Announcement over the intercom.)
18	to put in the IFU?	18	Q. (By Mr. Bentley) And you continue,
19	MR. KOOPMANN: Object to form.	19	"Ultimately I suspect J&J will pay out millions. I
20	A. No, I'd disagree. I've stated this many	20	am glad Biosurgery is keeping you busy"; is that
21	times that I don't think that's the role of the	21	correct?
22	IFU.	22	A. That's correct.
23		23	
	Q. (By Mr. Bentley) And I appreciate that. That wasn't my question exactly, though.		Q. Okay. So in December of 2011, it
24	rnat wasn't my question exactiv, though.	24	appears that you conveyed to Jonathan Fernandez at
25	Do you think it's helpful to have that	25	Ethicon that you were switching to biologicals; is

		<i>z</i> ,	
	Page 170		Page 172
1	that correct?	1	tell me about the Cochrane 2016 review?
2	A. That's correct.	2	A. I believe my answer was that there may
3	Q. Okay. And this is approximately eight	3	be some new articles. I wasn't absolute on that.
4	months before Prolift and Prolift+M are	4	I believe I stated that there were some articles
5	discontinued; isn't that correct?	5	that have been recently published that I may or may
6	A. That's correct.	6	not be aware of.
7	Q. And is it still your opinion that today	7	Q. And so were you aware of the Cochrane
8	you would be strike that.	8	2016 review when you earlier testified about which
9	Further down in the e-mail, you start out	9	articles you had reviewed subsequent to preparing
10	with, "I am starting to look at the AMS products in	10	your Prolift and Prolift+M reports?
11	Coloplast products again as it was our relationship	11	A. I did, and I believe I've already cited
12	that keep me with Ethicon for the past few years."	12	the 2016 Cochrane review a number of times in
13	And you state, "Ethicon is just way too slow to	13	today's deposition.
14	change their prolapse product line"; did I read	14	Q. Is there a reason that the 2016 Cochrane
15	that correctly?	15	review did not make it onto your reliance list?
16	A. That's correct.	16	A. This reliance list was prepared
17	Q. And do you have any understanding as to	17	primarily for the Delacruz case, which was in the
18	what you meant by "Ethicon was too slow to change	18	fall of 2015, so the reliance list was not updated,
19	their prolapse product line" that you stated in	19	I don't think, after that date, so it probably was
20	this e-mail?	20	not updated on any literature in 2016.
21	A. I do.	21	Q. Doctor, do you have your reliance list
22	Q. And what is that understanding?	22	available in front of you?
23	A. I had recommended to Ethicon that they	23	A. I do.
24	spend more time developing some of the biological	24	Q. I think it was previously entered in the
25	products similar to AMS and Coloplast and Boston	25	TVT-O deposition. I don't have another copy. I'm
	Page 171		Page 173
1	Scientific because it seemed to me that that's	1	not sure.
2	where the market was going, and also towards	2	MR. KOOPMANN: It's right there.
3	sacrocolpopexy. And they did not seem to be	3	Q. (By Mr. Bentley) On the second page of
4	developing products for either of those procedures.	4	your reliance list after the title page, at the
5	Q. And it was your recommendation that they	5	top, it says, "Flynn, Brian." That's you, right?
6	should go into biological products; isn't that	6	A. Yes.
7	correct?	7	Q. Okay. It says, "Materials list, updated
8	A. I thought it would be helpful, yes.	8	February 28, '16"; is that correct?
9	Q. And just to be clear, biological	9	A. That's correct.
10	products are not Prolift or Prolift+M, right?	10	Q. So what you just testified to is this
11	A. Correct.	11	materials list was, in fact, not updated in
12	Q. Doctor, in your report, you cite to the	12	February of this year like this document purports
13	2013 Cochrane review; isn't that correct?	13	that it was?
14	A. That's correct.	14	A. I can't say either way. There's a large
I	0 4 4 4 4 2015	l	volume of articles on this reliance list. If it
15	Q. Are you aware that there's a 2016	15	volume of articles on this remainer list. If it
15 16	Q. Are you aware that there's a 2016 Cochrane review?	16	says it was updated, it was updated, but the 2016
16	Cochrane review?	16	says it was updated, it was updated, but the 2016
16 17	Cochrane review? A. I am.	16 17	says it was updated, it was updated, but the 2016 review was missed.
16 17 18	Cochrane review? A. I am. Q. When did you become aware of that?	16 17 18	says it was updated, it was updated, but the 2016 review was missed. Q. Are there any other documents that you
16 17 18 19	Cochrane review? A. I am. Q. When did you become aware of that? A. Probably within the last few months, a	16 17 18 19	says it was updated, it was updated, but the 2016 review was missed. Q. Are there any other documents that you know of that were missed?
16 17 18 19 20	Cochrane review? A. I am. Q. When did you become aware of that? A. Probably within the last few months, a few months from when it was published.	16 17 18 19 20	says it was updated, it was updated, but the 2016 review was missed. Q. Are there any other documents that you know of that were missed? A. Anything published probably after
16 17 18 19 20 21	Cochrane review? A. I am. Q. When did you become aware of that? A. Probably within the last few months, a few months from when it was published. Q. Did we discuss earlier as to the whether	16 17 18 19 20 21	says it was updated, it was updated, but the 2016 review was missed. Q. Are there any other documents that you know of that were missed? A. Anything published probably after October 2015 could have been potentially missed.
16 17 18 19 20 21 22	Cochrane review? A. I am. Q. When did you become aware of that? A. Probably within the last few months, a few months from when it was published. Q. Did we discuss earlier as to the whether or not you were aware of any new articles that were	16 17 18 19 20 21	says it was updated, it was updated, but the 2016 review was missed. Q. Are there any other documents that you know of that were missed? A. Anything published probably after October 2015 could have been potentially missed. Q. So it's completely inaccurate that this

	Page 174		Page 176
1	A. No, that's not how I would describe it.	1	Dahlgren study?
2	Q. (By Mr. Bentley) Doctor, what date was	2	MR. KOOPMANN: Object to form.
3	your expert report signed?	3	A. I don't believe I'm familiar with it.
4	A. It was signed in February of 2016, I	4	Q. (By Mr. Bentley) Are you familiar with
5	believe.	5	the Delroy study?
6	Q. Do you know if the 2016 Cochrane review	6	A. Which study?
7	was published prior to you executing your report in	7	Q. The Delroy study.
8	this case?	8	MR. KOOPMANN: How do you spell that?
9	A. I believe it was.	9	MR. BENTLEY: D-e-l-r-o-y.
10	Q. Doctor, you've previously testified that	10	A. I don't believe so.
11	the Cochrane reviews are important pieces of	11	Q. (By Mr. Bentley) Okay. Are you
12	evidence in this case; isn't that true?	12	familiar with the Lamblin study, L-a-m-b-l-i-n?
13	A. That's true.	13	A. I would have to look at the article to
14	Q. So can you explain to me why you don't	14	be certain.
15	think it was important to include the 2016 Cochrane	15	Q. So you're not familiar with it as you
16	review regarding prolapse in your report?	16	sit here today?
17	MR. KOOPMANN: Object to form; misstates his	17	A. Correct.
18	testimony.	18	Q. Are you familiar with the Qatawneh,
19	A. I do think it's an important document.	19	Q-a-t-a-w-n-e-h, study?
20	Q. (By Mr. Bentley) And potentially the	20	A. No.
21	2016 Cochrane review, which you think is an	21	Q. Are you familiar with the Robert study
22	important document, could change your opinions in	22	published in 2014?
23	this case; isn't that correct?	23	A. No.
24	A. I don't think it's going to change my	24	Q. Are you familiar with the Rudnicki study
25	opinions very much, no.	25	published in 2014? R-u-d-n-i-c-k-i.
			•
	Page 175		Page 177
1	Q. Could it have changed your opinions in	1	A. No.
2			
	this case?	2	Q. Are you familiar with the Sung 2012
3	A. Could it have? There's always a	3	study? S-u-n-g.
3 4	A. Could it have? There's always a possibility, but I think it's unlikely that it	3	study? S-u-n-g. A. I'd have to go back and look at the
3 4 5	A. Could it have? There's always a possibility, but I think it's unlikely that it would have.	3 4 5	study? S-u-n-g. A. I'd have to go back and look at the reliance list.
3 4 5 6	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to	3	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's
3 4 5	 A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before 	3 4 5	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today,
3 4 5 6	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to	3 4 5 6	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it?
3 4 5 6 7	 A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before 	3 4 5 6 7	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today,
3 4 5 6 7 8	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before reaching your opinions in this case? MR. KOOPMANN: Object to form. A. Not necessarily. I feel that I had a	3 4 5 6 7 8	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it?
3 4 5 6 7 8	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before reaching your opinions in this case? MR. KOOPMANN: Object to form.	3 4 5 6 7 8	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it? A. Probably not familiar with it, then.
3 4 5 6 7 8 9	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before reaching your opinions in this case? MR. KOOPMANN: Object to form. A. Not necessarily. I feel that I had a wealth of information on a product that was very well-studied.	3 4 5 6 7 8 9	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it? A. Probably not familiar with it, then. Q. Do you think you need to add that study to your reliance list? A. I don't know one way or another.
3 4 5 6 7 8 9 10	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before reaching your opinions in this case? MR. KOOPMANN: Object to form. A. Not necessarily. I feel that I had a wealth of information on a product that was very	3 4 5 6 7 8 9 10	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it? A. Probably not familiar with it, then. Q. Do you think you need to add that study to your reliance list? A. I don't know one way or another. Q. Are you familiar with the 2014 Tamanini,
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3 4 5 6 7 8 9 10 11 12	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before reaching your opinions in this case? MR. KOOPMANN: Object to form. A. Not necessarily. I feel that I had a wealth of information on a product that was very well-studied. Q. (By Mr. Bentley) Do you know if the 2016 Cochrane review included a number of studies that weren't included in the 2013 review?	3 4 5 6 7 8 9 10 11 12	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it? A. Probably not familiar with it, then. Q. Do you think you need to add that study to your reliance list? A. I don't know one way or another. Q. Are you familiar with the 2014 Tamanini,
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before reaching your opinions in this case? MR. KOOPMANN: Object to form. A. Not necessarily. I feel that I had a wealth of information on a product that was very well-studied. Q. (By Mr. Bentley) Do you know if the 2016 Cochrane review included a number of studies that weren't included in the 2013 review? A. I don't know the answer to that. Q. Do you know if the 2016 Cochrane review included nine studies that weren't included in your	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it? A. Probably not familiar with it, then. Q. Do you think you need to add that study to your reliance list? A. I don't know one way or another. Q. Are you familiar with the 2014 Tamanini, T-a-m-a-n-i-n-i, study? A. As I stated earlier, there's a number of studies out that I can't possibly cite every single study in this report or on this reliance list. Q. So is it your testimony that you haven't
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before reaching your opinions in this case? MR. KOOPMANN: Object to form. A. Not necessarily. I feel that I had a wealth of information on a product that was very well-studied. Q. (By Mr. Bentley) Do you know if the 2016 Cochrane review included a number of studies that weren't included in the 2013 review? A. I don't know the answer to that. Q. Do you know if the 2016 Cochrane review included nine studies that weren't included in your reliance materials in preparation for this report?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	study? S-u-n-g. A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it? A. Probably not familiar with it, then. Q. Do you think you need to add that study to your reliance list? A. I don't know one way or another. Q. Are you familiar with the 2014 Tamanini, T-a-m-a-n-i-n-i, study? A. As I stated earlier, there's a number of studies out that I can't possibly cite every single study in this report or on this reliance list. Q. So is it your testimony that you haven't reviewed all the relevant literature related to
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Could it have? There's always a possibility, but I think it's unlikely that it would have. Q. Would you have liked an opportunity to adequately review the 2016 Cochrane review before reaching your opinions in this case? MR. KOOPMANN: Object to form. A. Not necessarily. I feel that I had a wealth of information on a product that was very well-studied. Q. (By Mr. Bentley) Do you know if the 2016 Cochrane review included a number of studies that weren't included in the 2013 review? A. I don't know the answer to that. Q. Do you know if the 2016 Cochrane review included nine studies that weren't included in your reliance materials in preparation for this report? A. I wasn't aware of that. Q. Do you know if you reviewed the Dahlgren	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I'd have to go back and look at the reliance list. Q. I'll represent to you that that study's not on your reliance list. As you sit here today, are you familiar with it? A. Probably not familiar with it, then. Q. Do you think you need to add that study to your reliance list? A. I don't know one way or another. Q. Are you familiar with the 2014 Tamanini, T-a-m-a-n-i-n-i, study? A. As I stated earlier, there's a number of studies out that I can't possibly cite every single study in this report or on this reliance list. Q. So is it your testimony that you haven't reviewed all the relevant literature related to Prolift and Prolift+M? MR. KOOPMANN: Object to form.
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	Page 178		Page 180
1	Do you know if you've reviewed all the	1	Cochrane 2016 review concludes that limited
2	relevant Prolift and Prolift+M literature in	2	evidence suggests that absorbable mesh may reduce
3	preparing your report and your opinions in this	3	rates of recurrent prolapse on examination compared
4	case?	4	to native tissue repair, but there was insufficient
5	A. I reviewed enough information to stand	5	evidence on absorbable mesh for us to draw any
6	behind my opinions in this report.	6	conclusions for other outcomes? Are you aware of
7	Q. And do you know if you reviewed or are	7	that?
8	you familiar with the Turgal 2013 study?	8	A. That the outcomes of absorbable mesh?
9	T-u-r-g-a-l.	9	Q. That there's limited evidence regarding
10	A. I'm not familiar with that study.	10	other outcomes associated with absorbable mesh.
11	Q. If any of those studies had reached	11	A. I never used absorbable mesh, and I
12	conclusions that were contrary to your opinions in	12	don't really talk about it in my report.
13	this case that you've presented in this report,	13	Q. Are you aware that Prolift+M has an
14	would that have affected your opinions here?	14	absorbable mesh component?
15	A. I don't think so.	15	A. It has a component, but it's you
16	Q. Is there anything out there in the	16	know, I thought you were referring to purely
17	medical literature that you haven't reviewed that	17	absorbable meshes like Vicryl mesh or Dexon mesh.
18	could possibly change your opinions here?	18	Q. So do you disagree with the conclusions
19	A. There's always possibilities, but I	19	in the 2016 Cochrane review?
20	think it's unlikely.	20	MR. KOOPMANN: Object to the form.
21	Q. And you just testified that those nine	21	A. I used the earlier Cochrane review to
22	studies that you haven't reviewed, that you don't	22	formulate my opinions in this report.
23	think any of those would have affected your	23	Q. (By Mr. Bentley) And the additional
24	opinions here; is that correct?	24	literature that we've discussed that you haven't
25	A. I think my opinion was that it's	25	reviewed doesn't affect or alter your opinions; is
	71. I think my opinion was that it's		Toviewed doesn't direct of diter your opinions, is
	Page 179		Page 181
1	unlikely that it would.	1	that correct?
2	Q. And if the 2016 Cochrane review, which	2	A. It does not.
3	you've testified that you've reviewed, if they	3	Q. And as you sit here today, do you have
4	identified these new studies that they thought were	4	any critiques or criticisms of the 2016 Cochrane
5	important to list if the Cochrane review thought	5	systematic review of the literature regarding
6	these studies were important to list out as being	6	transvaginal mesh or grafts compared with native
7	new additions to their studies since 2013, you	7	
8		'	tissue repair for vaginal prolapse? Do you have
l	don't agree that those studies were important in	8	tissue repair for vaginal prolapse? Do you have any criticisms or critiques of the systematic
9			
9 10	don't agree that those studies were important in	8	any criticisms or critiques of the systematic
	don't agree that those studies were important in reaching your opinion here; is that fair?	8	any criticisms or critiques of the systematic review published in 2016?
10	don't agree that those studies were important in reaching your opinion here; is that fair? A. That's fair.	8 9 10	any criticisms or critiques of the systematic review published in 2016? A. No.
10 11	don't agree that those studies were important in reaching your opinion here; is that fair? A. That's fair. Q. Are you aware that the 2016 Cochrane	8 9 10 11	any criticisms or critiques of the systematic review published in 2016? A. No. Q. And you've previously testified that
10 11 12	don't agree that those studies were important in reaching your opinion here; is that fair? A. That's fair. Q. Are you aware that the 2016 Cochrane review that you testified that you reviewed has	8 9 10 11 12	any criticisms or critiques of the systematic review published in 2016? A. No. Q. And you've previously testified that this is, in fact, one of the highest levels of
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10 11 12 13 14 15 16 17 18 19 20 21	don't agree that those studies were important in reaching your opinion here; is that fair? A. That's fair. Q. Are you aware that the 2016 Cochrane review that you testified that you reviewed has reached conclusions that the risk of mesh might not be outweighed by the benefits associated with recurrence in using Prolift or Prolift+M mesh kits? MR. KOOPMANN: Object to form. A. I'm aware of that, yes. Q. (By Mr. Bentley) And that doesn't affect your opinion here? A. I think I've stated my opinions very well, so I don't have any other opinions in regards to that.	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	any criticisms or critiques of the systematic review published in 2016? A. No. Q. And you've previously testified that this is, in fact, one of the highest levels of evidence available; is that correct? A. That's correct. MR. BENTLEY: I have no further questions right now, Doctor. Thank you. EXAMINATION BY MR. KOOPMANN: Q. Dr. Flynn, if the 2016 Cochrane review that plaintiffs' counsel's been asking you about says that awareness of prolapse at one to three years was less likely after mesh repair, is that

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	Page 182		Page 184
1	A. I believe so. Yes, it is.	1	A. Correct.
2	Q. (By Mr. Koopmann) And if the 2016	2	Q. So it was published for the whole world
3	Cochrane review that plaintiffs' counsel asked you	3	to see?
4	questions about says that rates of repeat surgery	4	A. I think very few people would see that.
5	for prolapse were lower in the mesh group, would	5	It's not a widely published or distributed journal.
6	that be consistent with your opinions regarding the	6	Q. But any doctor interested in learning
7	safety and efficacy of the Prolift and Prolift+M	7	about transvaginal mesh repair of anterior and
8	devices?	8	posterior vaginal wall prolapse could find that
9	MR. BENTLEY: Objection; form.	9	article?
10	A. Yes, it would.	10	A. Yes
11	Q. (By Mr. Koopmann) That statement is	11	MR. BENTLEY: Objection.
12	saying that mesh repairs help patients avoid the	12	A they could.
13	risks of reoperation that plaintiffs' counsel asked	13	Q. (By Mr. Koopmann) Your article that you
14	you about earlier; isn't that right?	14	co-authored with Dr. Terlecki written in the AUA
15	MR. BENTLEY: Objection; misstates, form,	15	update series in 2010, were you paid to write that
16	leading.	16	article?
17	A. That is correct.	17	A. A very small fee, yes.
18	Q. (By Mr. Koopmann) And if the 2016	18	Q. Do you recall what it was?
19	Cochrane review says that recurrent prolapse on	19	A. \$250. And I split that with
20	examination was less likely after mesh repair,	20	Dr. Terlecki.
21	would that be consistent with your opinions	21	Q. \$250 per hour?
22	regarding the Prolift and Prolift+M's safety and	22	A. No, total.
23	efficacy?	23	Q. And how long would you say you spent
24	MR. BENTLEY: Objection; form.	24	writing this article with Dr. Terlecki?
25	A. Yes, it would.	25	A. Well, the article's about 5,000 words,
	Page 183		Page 185
1	Q. (By Mr. Koopmann) And if the 2016	1	and we probably spent between 40 and 50 hours
2	Cochrane review by Dr. Maher and colleagues says	2	writing the article.
3	that there was no evidence of a difference between	3	Q. And did anyone from Ethicon ever talk to
4	the native tissue repair group and the mesh repair	4	you after they saw the article and ask you why you
5	group and the rates of de novo dyspareunia, would	5	wrote this article?
6	that be consistent with your opinions regarding the	6	MR. BENTLEY: Objection.
7	safety and efficacy of the Prolift and Prolift+M	7	A. Nobody talked to me before or after the
8	products?	8	article.
9	MR. BENTLEY: Objection.	9	Q. (By Mr. Koopmann) Did Ethicon continue
10	A. Yes, that would be.	10	to consult with you after the publication of this
11	Q. (By Mr. Koopmann) The question or	11	article?
12	plaintiffs' counsel asked you questions about this	12	A. Yes. As I stated earlier in the
13	e-mail that you sent to Jonathan Fernandez. Do you	13	deposition, I presented an exhibit of my consulting
14	recall these questions?	14	relationship going through 2011. I did the
15	A. I do.	15	TVT-Abbrevo video in 2011 after that article. I
16	Q. Did you suggest that Ethicon pursue	16	was part of the TVT Exact launch, so I still
17	blockage products or abdominal sacrocolpopexy	17	continued to consult after that publication.
18	products because you thought those were safer than	18	Q. And did you keep all of the \$250 that
l	transvaginal mesh products?	19	you were paid for writing this article we marked as
19		1	Exhibit 7?
20	MR. BENTLEY: Objection.	20	EXHIBIT /!
		20	A. No, I shared half of it with my fellow,
20	MR. BENTLEY: Objection.		
20 21	MR. BENTLEY: Objection. A. No.	21	A. No, I shared half of it with my fellow,
20 21 22	MR. BENTLEY: Objection.A. No.Q. (By Mr. Koopmann) The Velemir study	21 22	A. No, I shared half of it with my fellow, Ryan Terlecki.

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	Page 186		Page 188
1	article at for \$125, that'd be about \$3 per hour	1	of delayed failures after POP surgery while
2	you got for writing this article; is that about	2	transvaginal placement minimizes postoperative
3	right?	3	morbidity." Do you still stand by those opinions?
4	MR. BENTLEY: Objection.	4	MR. BENTLEY: Objection.
5	A. That's right. We don't write these	5	A. I do.
6	articles for monetary gain.	6	Q. (By Mr. Koopmann) Or that statement, I
7	Q. (By Mr. Koopmann) Why did you write	7	should say.
8	this article?	8	MR. BENTLEY: Objection.
9	A. Well, first off, I was asked to write it	9	A. I do, very much so.
10	by the American Urologic Association. The American	10	Q. (By Mr. Koopmann) And you went on to
11	Urologic Association was getting a number of phone	11	say, "Superior cure rates with mesh are contrasted
12	calls from its members about how it should	12	with the introduction of unique and sometimes
13	interpret and respond to the FDA Public Health	13	serious graft complications. Therefore, reinforced
14	Notification of 2008. They asked us to provide	14	pelvic floor repairs should only be performed in
15	useful information. The AUA Update series is a CME	15	well-selected patients after they provide informed
16	series, so that's a CME document, that's why	16	consent"; is that right?
17	there's questions and answers at the end of the	17	MR. BENTLEY: Objection; leading.
18	document. That's why there's parts bolded so	18	Q. (By Mr. Koopmann) That's what you said?
19	people who read the document can read all of it or	19	A. That's what I said.
20	some of it. Most of the questions in that paper	20	Q. Do you feel like you were objective in
21	come from the bolded area, so we're asked to	21	writing this report?
22	intentionally bold a certain percentage of the	22	MR. BENTLEY: Objection.
23	paper. So that was intended as an instrument to	23	Q. (By Mr. Koopmann) Or this article?
24	educate my colleagues, residents, fellows,	24	A. Absolutely. I disclosed my conflicts of
25	physicians in practice about polypropylene mesh,	25	interest on the front page. The article was
	Page 187		Page 189
1	about incontinence, prolapse, and the FDA Public	1	reviewed by three reviewers. I responded to the
2	Health Notification.	2	reviews. And I do feel that this article was an
3	Q. (By Mr. Koopmann) And plaintiffs'	3	objective piece of information.
4	counsel asked you some questions about a sentence	4	Q. And do you think it is the case that
5	that says, "Patient factors that may lead to an	5	native tissue repairs for pelvic organ prolapse
6	increased risk for extrusion include age, estrogen	6	should only be performed in well-selected patients
7	status, prior radiation, active vaginal infection,	7	after they provide informed consent?
8	smoking, obesity, immunosuppression, diabetes, and	8	MR. BENTLEY: Objection; form, leading.
9	concomitant hysterectomy"; do you remember that?	9	A. Yes. Any time you perform any kind of
10	A. I do.	10	surgery, you want to make sure you properly select
11	Q. And the next sentence you wrote says,	11	your patient regardless what the surgery is and
12	"Many patients with adverse implantation features	12	what procedure you select. You want to be very
13	also have weak connective tissue and are at high	13	careful in that procedure selection.
14	risk for failure if a graft is not used," is that	14	Q. (By Mr. Koopmann) The article marked as
15	right?	15	Exhibit 6 by Dr lead author, or first listed
16	A. That's correct.	16	author, Beri Ridgeway, that's titled "Early
17	Q. Do you still stand by that opinion today	17	experience with mesh excision for adverse outcomes
18	as well?	18	after transvaginal mesh placement using prolapse
19	A. I do.	19	kits," is that right?
		20	A. That's correct.
20	Q. In the summary of this article that's		
21	been marked as Exhibit 7, you say in bold print,	21	Q. That's from December 2008?
22	"Surgeons with diverse backgrounds have been able	22	A. Yes.
23	to achieve excellent results in primary and	23	Q. So that's eight years old at this point,
24	secondary repairs for SUI with polypropylene mesh.	24	almost?
25	Similarly, mesh reinforcement reduces the incidence	25	MR. BENTLEY: Objection.
		1	

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	Page 190		Page 192
1	A. Correct.	1	that sexual function based on the prolapse and
2	Q. (By Mr. Koopmann) You were asked some	2	incontinence sexual questionnaire scores was
3	questions about RCT by Dr. Cheryl Iglesia, Andrew	3	similar before the procedure between mesh and
4	Sokol and others that was marked as Exhibit 4. Do	4	no-mesh groups, and improved significantly in both
5	you recall those questions?	5	groups 12 months after the procedure; is that
6	A. I do.	6	right?
7	Q. In preparing your opinions regarding the	7	MR. BENTLEY: Objection.
8	Prolift and Prolift+M devices, did you also review	8	A. Yes, that's right.
9	and rely on RCT by Andrew Sokol and Cheryl Iglesia	9	Q. (By Mr. Koopmann) And they found that
10	and others on their one-year outcomes following	10	there was no significant difference between the
11	native tissue repair versus mesh repair?	11	groups with regards to sexual function 12 months
12	MR. BENTLEY: Objection; form, leading,	12	after the procedure; is that right?
13	compound.	13	A. Yes, that's right.
14	A. Yeah, that's cited in my report, the one	14	Q. They also noted that in the group of
15	one-year objective and functional outcomes of	15	patients who did not have mesh, 15 percent had
16	randomized clinical trial of vaginal mesh for	16	apical Gor-Tex suture exposures; is that right?
17	prolapse.	17	MR. BENTLEY: Objection.
18	Q. (By Mr. Koopmann) And they studied 32	18	A. That's correct.
19	women who had a mesh repair and 33 women who had a	19	Q. (By Mr. Koopmann) And two women
20	traditional repair; is that right?	20	complained of vaginal discharge and required suture
21	MR. BENTLEY: Same objection.	21	removal in the office at six and nine months after
22	A. Yes, that's correct.	22	the procedure?
23	Q. (By Mr. Koopmann) And they found that	23	MR. BENTLEY: Objection.
24	the quality of life improved and did not differ	24	A. Correct.
25	between the two groups, 96.2 percent in the mesh	25	Q. (By Mr. Koopmann) They found no
	Page 191		Page 193
1	group and 90.9 percent in the no-mesh group; is	1	statistically significant differences between the
2	that right?	2	mesh and no-mesh groups with respect to long-term
3	MR. BENTLEY: Same objection.	3	complications, did they?
4	A. That's correct.	4	MR. BENTLEY: Objection.
5	Q. (By Mr. Koopmann) Those are the	5	A. That's correct.
6	percentages of the subjects that reported a cure of	6	Q. (By Mr. Koopmann) And, in fact, even
7	bulge symptoms; is that right?	7	based on their three-month outcomes that were
8	MR. BENTLEY: Same objection.	8	reported on Exhibit 4, they noted that subjective
9	A. Yes, that's correct.	9	quality-of-life measurements did not differ between
10	Q. (By Mr. Koopmann) They also reported	10	the two groups at baseline or three months
11	that postoperative subjective quality-of-life	11	postoperatively; is that right?
12	measurements showed statistically significant	12	MR. BENTLEY: Objection.
13	improvements from baseline for both the mesh and	13	A. That's right.
14	no-mesh groups for almost all quality-of-life	14	Q. (By Mr. Koopmann) The "Adverse
15	measurements and did not differ between the two	15	Reactions" section of the Prolift IFU indicates
16	groups one year after the procedure; is that right?	16	that potential adverse reactions are those
17	MR. BENTLEY: Objection.	17	typically associated with surgically implantable
1	A. Yes, that's right.	18	materials, including infection potentiation,
18	11. 105, 11.00 5 11.01.		inflammation, adhesion formation, fistula
18 19	Q. (By Mr. Koopmann) And is that	19	ilitalililation, adhesion formation, fistura
	-	19 20	formation, erosion, extrusion, and scarring that
19	Q. (By Mr. Koopmann) And is that		
19 20	Q. (By Mr. Koopmann) And is that consistent with your opinions regarding the safety	20	formation, erosion, extrusion, and scarring that
19 20 21	Q. (By Mr. Koopmann) And is that consistent with your opinions regarding the safety and efficacy of the Prolift device?	20 21	formation, erosion, extrusion, and scarring that results in implant contraction; is that correct?
19 20 21 22	Q. (By Mr. Koopmann) And is that consistent with your opinions regarding the safety and efficacy of the Prolift device? MR. BENTLEY: Objection.	20 21 22	formation, erosion, extrusion, and scarring that results in implant contraction; is that correct? MR. BENTLEY: Objection; form, foundation,

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	Page 194		Page 196
1	pelvic floor surgeons would know, based on that	1	MR. KOOPMANN: Mark this as whatever the
2	sentence that I just read, that that pain is a	2	next exhibit is, please.
3	possibility with the implantation of a Prolift	3	(Exhibit 10 was marked for identification.)
4	device?	4	Q. (By Mr. Koopmann) Handing you what's
5	MR. BENTLEY: Objection; form, leading,	5	been marked as Deposition Exhibit 10, do you
6	foundation, speculation.	6	recognize this document?
7	A. Yes, absolutely.	7	A. I do.
8	Q. (By Mr. Koopmann) And is it fundamental	8	Q. What is it?
9	medical and surgical knowledge that pain can result	9	A. This is a Gynecare Prolift Surgeon's
10	after any surgery, whether it's a mesh surgery or	10	Resource Monograph. This is a document that was
11	nonmesh surgery?	11	published by high-volume Prolift users to help
12	MR. BENTLEY: Objection.	12	physicians in practice understand some of the
13	A. Any kind of surgery, yes.	13	technical pearls that some of the surgeons that had
14	Q. (By Mr. Koopmann) And is it fundamental	14	done a significant amount of Prolift procedures to
15	medical knowledge that if pain results after a	15	share their experience with the device.
16	surgery, it could be mild or moderate or severe?	16	Q. And this was provided by Ethicon?
17	MR. BENTLEY: Same objection.	17	A. It was.
18	A. That's correct.	18	Q. And was it made available to pelvic
19	Q. (By Mr. Koopmann) And is it also	19	floor surgeons?
20	fundamental medical knowledge that if pain results	20	MR. BENTLEY: Objection.
21	after a surgery, that the pain could be temporary	21	A. Yes, it was. That was the intent of the
22	or permanent?	22	report.
23	MR. BENTLEY: Objection.	23	Q. (By Mr. Koopmann) Is there anything
24	A. That's correct.	24	like this Surgeon's Resource Monograph that exists
25	Q. (By Mr. Koopmann) Permanent pain can	25	for native tissue repairs?
	P 105		D 107
1	Page 195 result after a native tissue repair, can it?	1	Page 197 MR. BENTLEY: Objection.
2	MR. BENTLEY: Objection.	2	A. No.
3	A. Correct.	3	Q. (By Mr. Koopmann) Does this Surgeon's
4	Q. (By Mr. Koopmann) Can dyspareunia result	4	Resource Monograph discuss various complications
5	after a native tissue repair?	5	possible with the Prolift surgery?
6	A. That's correct.	6	MR. BENTLEY: Objection.
7	Q. Can an infection occur in a native		MR. BENTLET. Objection.
/		1 7	A It does And I've wood one of the
0		7	A. It does. And I've used one of the
8	tissue repair?	8	tables from the monograph in my report.
9	tissue repair? MR. BENTLEY: Objection.	8 9	tables from the monograph in my report. Q. (By Mr. Koopmann) Like the table at
9 10	tissue repair? MR. BENTLEY: Objection. A. Correct.	8 9 10	tables from the monograph in my report. Q. (By Mr. Koopmann) Like the table at page 10?
9 10 11	tissue repair? MR. BENTLEY: Objection. A. Correct. Q. (By Mr. Koopmann) The IFU also notes	8 9 10 11	tables from the monograph in my report. Q. (By Mr. Koopmann) Like the table at page 10? A. That's correct.
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9 10 11 12 13	tissue repair? MR. BENTLEY: Objection. A. Correct. Q. (By Mr. Koopmann) The IFU also notes that punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during Gynecare	8 9 10 11 12 13	tables from the monograph in my report. Q. (By Mr. Koopmann) Like the table at page 10? A. That's correct. Q. And that provides a citation to eight studies in the top table setting forth how many
9 10 11 12 13	tissue repair? MR. BENTLEY: Objection. A. Correct. Q. (By Mr. Koopmann) The IFU also notes that punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during Gynecare Prolift guide passage and may require surgical	8 9 10 11 12 13	tables from the monograph in my report. Q. (By Mr. Koopmann) Like the table at page 10? A. That's correct. Q. And that provides a citation to eight studies in the top table setting forth how many patients were involved in the studies, what the
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9 10 11 12 13 14 15 16 17 18	tissue repair? MR. BENTLEY: Objection. A. Correct. Q. (By Mr. Koopmann) The IFU also notes that punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during Gynecare Prolift guide passage and may require surgical repair; is that right? A. Yes, that's right. Q. And does that sentence also tell you and other surgeons that pain could result from implantation of the Prolift device? MR. BENTLEY: Objection. A. That's correct.	8 9 10 11 12 13 14 15 16 17 18 19 20 21	tables from the monograph in my report. Q. (By Mr. Koopmann) Like the table at page 10? A. That's correct. Q. And that provides a citation to eight studies in the top table setting forth how many patients were involved in the studies, what the follow-up period was, what the exposure rates were what the success rates were, and some of the other complications that occurred in connection with the use of the Prolift devices, correct? MR. BENTLEY: Objection. A. That's correct. It has a total of 549 patients, six-month follow-up, exposure rate
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	Page 198		Page 20
1	Q. (By Mr. Koopmann) Some of the exposure	1	is that right?
2	rates reported are you know, the Rivera study	2	MR. BENTLEY: Objection; form, foundation
3	shows an 11.7 exposure rate?	3	leading.
4	MR. BENTLEY: Objection.	4	A. Yes, that's correct.
5	A. That's correct.	5	Q. (By Mr. Koopmann) And they also noted
6	Q. (By Mr. Koopmann) The page opposite	6	that awareness of prolapse was also higher after
7	that, there's a discussion of dyspareunia and	7	the anterior repair as compared to the
8	vaginal pain that can occur; is that correct?	8	polypropylene mesh repair; is that right?
9	A. That's correct.	9	MR. BENTLEY: Same objection.
10	Q. Is this a document that you found	10	A. Yes, that's correct.
11	helpful in your practice?	11	Q. (By Mr. Koopmann) They also noted,
12	MR. BENTLEY: Objection.	12	however, the reoperation rate for prolapse was
13	A. It is.	13	similar at 14 out of 459, 3 percent, after the
14	Q. (By Mr. Koopmann) Have you seen a	14	native tissue repair compared to 6 out of 470, 1.3
15	decrease in efficacy in the patients that you've	15	percent, after the anterior polypropylene mesh
16	treated for pelvic organ prolapse, let's say for	16	repair, and no differences in quality-of-life data
17		17	or de novo dyspareunia were identified; is that
	cystoceles, since you stopped using Prolift and		
18	Prolift+M?	18	right?
L9	MR. BENTLEY: Objection.	19	MR. BENTLEY: Same objection.
20	A. Can you repeat the question?	20	A. That's correct.
21	Q. (By Mr. Koopmann) Have you seen a	21	Q. (By Mr. Koopmann) And the mesh erosion
22	decrease in efficacy in the patients that you've	22	rate reported there was 11.4 percent?
23	treated for pelvic organ prolapse, let's say for	23	MR. BENTLEY: Same objection.
24	cystoceles, since you stopped using Prolift and	24	A. Yes.
25	Prolift+M?	25	Q. (By Mr. Koopmann) Which was 64 out of
	Page 199		Page 20
1	MR. BENTLEY: Same objection.	1	563 patients?
2	A. Yes, I have.	2	MR. BENTLEY: Same objection.
3	Q. (By Mr. Koopmann) And is that one of	3	A. That's correct.
4	the reasons that you would still like to have the	4	Q. (By Mr. Koopmann) And then surgical
5	ability to use Prolift or Prolift+M in certain	5	interventions were performed in 6.8 percent of the
6			
7	patients?	6	patients?
/	patients? MR. BENTLEY: Objection: form, leading.	6	patients? MR. BENTLEY: Objection.
	MR. BENTLEY: Objection; form, leading.	7	MR. BENTLEY: Objection.
8	MR. BENTLEY: Objection; form, leading. A. Correct.	7 8	MR. BENTLEY: Objection. A. That's correct.
8 9	MR. BENTLEY: Objection; form, leading. A. Correct. Q. (By Mr. Koopmann) And is the same true	7 8 9	MR. BENTLEY: Objection. A. That's correct. Q. (By Mr. Koopmann) You relied on an
8 9 10	MR. BENTLEY: Objection; form, leading. A. Correct. Q. (By Mr. Koopmann) And is the same true for rectocele repairs?	7 8 9 10	MR. BENTLEY: Objection. A. That's correct. Q. (By Mr. Koopmann) You relied on an article by Dr. Svabik, and others, that's in RCT
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	Page 202		Page 204
1	one case of anatomical failure in the Prolift group	1	quality-of-life scores revealed greater improvement
2	and 22 cases of anatomical failure in the	2	in the mesh group; is that right?
3	sacrospinous fixation group; is that right?	3	MR. BENTLEY: Objection.
4	MR. BENTLEY: Same objection.	4	A. Yes, that's right.
5	A. That's correct.	5	Q. (By Mr. Koopmann) They also noted on
6	Q. (By Mr. Koopmann) So the anatomical	6	page well, it's the second-to-last page, I don't
7	failure rate in the Prolift group was 3 percent,	7	know if it's numbered, "On analysis of this study,
8	and the anatomical failure rate in the native	8	one must take into account that, although the
9	tissue repair group was 64 percent?	9	tested mesh product, Prolift, has been withdrawn
10	A. That's correct.	10	from the world market, its material has the optimal
11	MR. BENTLEY: Objection.	11	properties of a mesh for pelvic floor repairs"; is
12	Q. (By Mr. Koopmann) And that difference	12	that right?
13	was statistically significant?	13	MR. BENTLEY: Objection.
14	MR. BENTLEY: Objection.	14	A. That's right.
15	A. Yes, it was.	15	Q. (By Mr. Koopmann) They included a
16	Q. (By Mr. Koopmann) Is this an article	16	table, numbered Table 6, that set forth
17	that you relied on in forming your opinions	17	complications and complaints at one-year follow-up,
18	regarding the safety and efficacy of the Prolift	18	and it indicated that 6.2 percent of the native
19	device?	19	tissue patients had dyspareunia at one-year
20	A. Yes.	20	follow-up, and 3.4 percent of the patients had
21	Q. They also reported that sexual activity	21	dyspareunia in the mesh group; is that right?
22	was not influenced by the type of surgery; is that	22	MR. BENTLEY: Objection.
23	right?	23	A. Yes, that's right.
24	MR. BENTLEY: Objection.	24	Q. (By Mr. Koopmann) And pain was
25	A. That's correct.	25	experienced by 8.6 percent of the women in the
23	A. That's correct.	23	experienced by 8.0 percent of the women in the
	Page 203		Page 205
1	Q. (By Mr. Koopmann) You also relied on an	1	native tissue group at one-year follow-up, but only
2	article by an RCT by lead author with the last	2	2.3 percent in the mesh group; is that also right?
3	name da Silveira; is that correct?	3	MR. BENTLEY: Objection.
4	A. That's correct.	4	A. Yes, that's right.
5	Q. And in that study, they looked at 184	5	Q. (By Mr. Koopmann) Is it fair to say
6	women with POPQ stage 3 or 4 prolapse who were	6	that there are randomized control trials regarding
7	randomly assigned to undergo surgical treatment	7	the Prolift device that report both very positive
8	using either native tissue repair or synthetic mesh	8	things about the Prolift device and not-so-positive
9			8- manage F
	repair with Prolift; is that right?	9	things about the Prolift device?
10	repair with Prolift; is that right? MR. BENTLEY: Objection.	9	_
10 11			things about the Prolift device?
	MR. BENTLEY: Objection.	10	things about the Prolift device? MR. BENTLEY: Objection; form.
11	MR. BENTLEY: Objection. A. Yes, that's correct.	10 11	things about the Prolift device? MR. BENTLEY: Objection; form. A. Yes, that's correct.
11 12	MR. BENTLEY: Objection.A. Yes, that's correct.Q. (By Mr. Koopmann) And at one year,	10 11 12	things about the Prolift device? MR. BENTLEY: Objection; form. A. Yes, that's correct. MR. BENTLEY: Compound, leading,
11 12 13	MR. BENTLEY: Objection. A. Yes, that's correct. Q. (By Mr. Koopmann) And at one year, follow-up anatomical cure rates were better in the	10 11 12 13	things about the Prolift device? MR. BENTLEY: Objection; form. A. Yes, that's correct. MR. BENTLEY: Compound, leading, speculation.
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	Page 206		Page 208
1	A. Yes.	1	tissue repair, sacrocolpopexy and graph-augmented
2	Q. And you hold the opinions set forth in	2	repairs with biologicals.
3	your Prolift and Prolift+M reports to a reasonable	3	Q. (By Mr. Koopmann) Even if you didn't do
4	degree of medical certainty?	4	a systematic review of your case log, do you,
5	A. I do.	5	nonetheless, have a good understanding of the
6	Q. Why is it that you didn't ask to see	6	complication rates that you saw in your practice
7	internal corporate depositions of Ethicon	7	using the Prolift and Prolift+M devices?
8	personnel?	8	MR. BENTLEY: Objection; form, foundation,
9	A. Because I didn't think it was relevant	9	speculation.
10	to me in formulating my opinions in preparing this	10	A. Yes, I am aware.
11	report.	11	Q. (By Mr. Koopmann) And are those
12	Q. Did you rely on higher-level evidence	12	complication rates the same ones that you would
13	than internal corporate depositions?	13	report to patients who asked you about
14	A. I did. Depositions are not levels of	14	complications when considering possibly having a
15	evidence. They're a person's response to questions	15	Prolift or Prolift+M surgery?
16	that they were asked. We relied on randomized	16	MR. BENTLEY: Same objection.
17	control trials, meta-analyses and systematic	17	A. Yes. When most surgeons are discussing
18	reviews primarily in preparation of this report.	18	risks and benefits of a procedure with their
19	Q. Is it true that sometimes two authors	19	patients, they're using both their own personal
20	setting out to review a body of literature, let's	20	experience and then what the medical literature
21	say, for purposes of a systematic review of	21	shows.
22	literature end up reviewing somewhat different	22	Q. (By Mr. Koopmann) Was the literature
23	bodies of literature for whatever reason?	23	search that you performed for purposes of the
24	MR. BENTLEY: Objection; form, date,	24	preparation of your Prolift and Prolift+M
25	speculation, foundation.	25	reports was it the same basic methodology that
	Page 207		D 200
1	Page 207 A. Absolutely. There can be biases even in	1	Page 209 you use in doing literature searches for purposes
2	systematic reviews. And so just like I've been	2	of your clinical practice?
3	questioned about why I selected which articles to	3	MR. BENTLEY: Objection.
4	review here, the reviewers of a systematic review	4	A. Yes, clinical practice and publications.
5	-	5	A. Tes, chinical practice and publications.
]			O (Ry Mr. Koopmann) Is there any reliable
6	have the ability to pick and choose which articles		Q. (By Mr. Koopmann) Is there any reliable
6	they want to include in their systematic review.	6	literature that you're aware of that suggests that
7	they want to include in their systematic review. Q. (By Mr. Koopmann) You talked earlier	6 7	literature that you're aware of that suggests that Gynemesh PS or Ultrapro mesh is toxic or
7 8	they want to include in their systematic review. Q. (By Mr. Koopmann) You talked earlier about your case log, and I think you indicated	6 7 8	literature that you're aware of that suggests that Gynemesh PS or Ultrapro mesh is toxic or carcinogenic?
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	Page 210		Page 212
1	a certain surgical intervention; is that true?	1	after a native tissue repair?
2	MR. BENTLEY: Objection to form; foundation,	2	MR. BENTLEY: Same objection.
3	leading, compound.	3	A. Yes, it can.
4	A. Correct. The goal of a systematic	4	Q. (By Mr. Koopmann) Pull up your Prolift
5	review is to select articles that meet a certain	5	report. You've got it in front of you.
6	criteria for inclusion, and whether those report	6	Plaintiffs' counsel asked you earlier why
7	positive or negative outcome shouldn't influence	7	you didn't reference or discuss infection in your
8	the selection of those articles.	8	Prolift report. Do you remember that?
9	Q. (By Mr. Koopmann) Can adding	9	MR. BENTLEY: Objection; misstates.
10	information to an IFU potentially be unhelpful?	10	A. I do.
11	MR. BENTLEY: Objection; form, foundation.	11	Q. (By Mr. Koopmann) Turn to page 14,
12	A. Yes.	12	please. The bottom paragraph there, you talk about
13	Q. (By Mr. Koopmann) How so?	13	how native tissue repairs can cause infection; is
14	A. Well, if there's too much information in	14	that right?
15	the IFU, just like that package insert you get at	15	A. Correct.
16	your pharmacy, you're less likely to read it. So	16	Q. And if you'll turn to I'm sorry.
17	there's a danger of information overload,	17	Okay. You're on 14?
18	especially in today's era. So I think that that	18	A. Yes.
19	information may not be looked at if there's too	19	Q. Okay. That question was actually about
20	much information there, or surgeons might not read	20	page 10.
21	it in its entirety.	21	A. Okay.
22	MR. BENTLEY: Move to strike, speculation.	22	Q. Did you talk about the risk of infection
23	Q. (By Mr. Koopmann) If too much	23	with native tissue repairs?
24	information is included in an IFU, do you think it	24	A. Yes. It says, "In summary, native
25	could potentially obscure other important	25	tissue repairs can cause numerous complications,
	Page 211		Page 213
1	information?	1	such as bleeding, infection, dyspareunia, pain,
2	MR. BENTLEY: Objection; form, foundation,	2	injury to surrounding organs, including bladder,
3	speculation.	3	bowel, rectum, or ureter. More damage or
4	A. Yes, I think the important information	4	entrapment can occur leading to chronic pain,
5	may be overlooked if the person reading the IFU is	5	chronic groin or buttock pain."
6	not reading every word of the IFU.	6	Q. Now turn to page 14, please. The
7	Q. (By Mr. Koopmann) Do you need	7	second-to-last full paragraph, you indicate the
8	information included in an IFU that you learned in	8	pore size of Gynemesh PS is about 2.5 millimeters
9	medical school and residency?	9	or 2,500 microns, which easily accommodates the
10	A. No.	10	cells and small blood vessels needed to access the
11	Q. Do you need all surgical complications	11	pores, promote tissue integration and reduce the
1			
12	to be included in an IFU?	12	risk of infection; is that correct?
13	MR. KOOPMANN: Objection.	13	A. That's correct.
13 14	MR. KOOPMANN: Objection.A. I do not, nor is that even possible or	13 14	A. That's correct.Q. So you're noting there that there is a
13 14 15	MR. KOOPMANN: Objection. A. I do not, nor is that even possible or relevant.	13 14 15	A. That's correct.Q. So you're noting there that there is a risk of infection with the Gynemesh PS; is that
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13 14 15 16 17	MR. KOOPMANN: Objection. A. I do not, nor is that even possible or relevant. Q. (By Mr. Koopmann) Can vaginal shortening occur after a native tissue repair?	13 14 15 16 17	A. That's correct. Q. So you're noting there that there is a risk of infection with the Gynemesh PS; is that true? A. That's true.
13 14 15 16 17 18	MR. KOOPMANN: Objection. A. I do not, nor is that even possible or relevant. Q. (By Mr. Koopmann) Can vaginal shortening occur after a native tissue repair? MR. BENTLEY: Objection.	13 14 15 16 17 18	 A. That's correct. Q. So you're noting there that there is a risk of infection with the Gynemesh PS; is that true? A. That's true. Q. And turn to page 20, please. You note
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A. Yes, Q. Is it a good idea for a doctor to try to mitigate factors that could cause a wound complication before doing a native tissue surgery? A. Yes. Q. So for instance, if a patient was a smoker and came to you and the two of you agreed that she was going to have a native tissue surgery for her pelvic organ prolapse, it would be a good idea to counsel her to stop smoking for that reason, and others? MR. BENTILEY: Objection; form, leading. A. For that reason, and others. I talk about smoking cessation with all my patients regardless of the surgeries. Q. (By Mr. Koopmann) Is it a surgeon's responsibility to make sure he or she is familiar with the steps for implanting a medical device? Q. (By Mr. Koopmann) Can contracted scar dissue occur in a native tissue repair? MR. BENTLEY: Objection: form, foundation. A. Yes. Q. (By Mr. Koopmann) If that occurs in a Page 215 mative tissue repair, can it cause pain? MR. BENTLEY: Objection. A. Yes. Q. (By Mr. Koopmann) Can nerve injury RM. BENTLEY: Objection. A. Yes. Q. (By Mr. Koopmann) Can nerve injury result from a native tissue repair? A. Yes. Q. (By Mr. Koopmann) Can nerve injury result from a native tissue repair? A. Yes. Q. (By Mr. Koopmann) Can nerve injury result from a native tissue repair? A. Yes. Q. (By Mr. Koopmann) Can nerve injury result from a native tissue repair; A. Yes. Q. (By Mr. Koopmann) Can nerve injury result from a native tissue repair? A. Yes. Q. (By Mr. Koopmann) Can nerve injury result from a native tissue repair; A. Yes. Q. (By Mr. Koopmann) Can nerve injury result from a native tissue repair; A. Yes. Q. (By Mr. Koopmann) Can nerve injury result from a native tissue repair; A. Yes. Q. (By Mr. Koopmann) Can nerve injury result from a native tissue professional deucation for Ethicon regarding Prolift; is that right? A. Yes, that's correct. Q. (By Mr. Koopmann) Day ou think tha complications that you saw in your clinical procedures: A. Yes, that's correct. Q. (By Mr. Koopmann) Day ou to do that? A. Yes. Q. (By Mr. Koopmann) Can nerve injury resu			<i>y</i> ,	
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A. Yes. Q. So for instance, if a patient was a you and the two of you agreed that she was going to have a native tissue surgery for her pelvic organ prolapse, it would be a good that she was going to have a native tissue surgery for her pelvic organ prolapse, it would be a good that she was going to have a native tissue surgery for her pelvic organ prolapse, it would be a good to die at counsel her to stops snoking for that the University of Colorado how to implant reason, and others? MR. BENTLEY: Objection; form, leading. Regions in the steps for implanting a medical device? MR. BENTLEY: Objection; form, foundation. A. Yes. Q. (By Mr. Koopmann) Is it a surgeon's tissue occur in a native tissue repair? MR. BENTLEY: Objection; form, foundation. A. Yes. Q. (By Mr. Koopmann) If that occurs in a Page 215 native rissue repair, can it cause pain? MR. BENTLEY: Objection. A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair; A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair; A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair; A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair; A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair real A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair; A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair real A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair real A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair real A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair real A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair real Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair	3	_	3	
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MR. BENTLEY: Objection; form, foundation. A. Yes. Q. (By Mr. Koopmann) Can contracted scar tissue occur in a native tissue repair? A. Yes. Q. (By Mr. Koopmann) If that occurs in a Page 215 mative tissue repair, can it cause pain? A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair cause pain? A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair cause pain? A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair cause pain? A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair cause pain? A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair cause pain? A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair cause pain? A. Yes. Q. (By Mr. Koopmann) Can excessive tension from sutures used in a native tissue repair cause pain? A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. (By Mr. Koopmann) Optou think that felt was the ideal mesh. Q. (By Mr. Koopmann) Can nerve injury A. Yes. Q. You performed some professional A. Yes. Q. You performed some professional A. Yes. A. Yes, that's correct. Q. (By Mr. Koopmann) Do you think that complications reported in the IFUs for the Prol and Prolift+M devices are consistent with the complications that you saw in your clinical practice using those devices? A. Because I enjoy teaching. It's always Light Provided Scalar and physicians in practice. I A. Yes, that is consistent.	18	with the steps for implanting a medical device?	18	fellows at the University of Colorado to implant
20 A. Yes. 21 Q. (By Mr. Koopmann) Can contracted scar tissue occur in a native tissue repair? 22 tissue occur in a native tissue repair? 23 MR. BENTLEY: Objection; form, foundation. 24 A. Yes. 25 Q. (By Mr. Koopmann) If that occurs in a 26 Page 215 27 Intivity of the product	19		19	Prolift and Prolift+M devices, among other prolapse
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	25	practice learn how to do new procedures. I felt	25	warnings in the Prolift, the Prolift+M IFUs on all

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	Page 218		Page 220
1	of your experience, education, training and review	1	that this is the most recent and largest systematic
2	of the literature?	2	review of all the available prolapse and
3	MR. BENTLEY: Objection.	3	Prolift-related literature?
4	A. That is correct.	4	A. I don't have knowledge if that's the
5	Q. (By Mr. Koopmann) Is Gynemesh PS the	5	largest. As meta-analyses are published, the more
6	most studied mesh for use in prolapse surgery?	6	recent ones tend to have more data as they collect
7	MR. BENTLEY: Objection; form, foundation,	7	more data, as more studies are published, so that's
8	speculation.	8	a general observation I would have.
9	A. Yes, it is.	9	Q. And this is more recent than the 2013
10	MR. KOOPMANN: Those are all the questions I	10	Cochrane review that you cite in your report; isn't
11	have for you, Dr. Flynn.	11	that correct?
12	EXAMINATION	12	A. That's correct.
13	BY MR. BENTLEY:	13	Q. And this study, in fact, has
14	Q. Dr. Flynn, just a couple follow-ups.	14	approximately nine additional studies that weren't
15	In the 2016 Cochrane review that you've	15	included in the 2013 Cochrane view; isn't that
16	reviewed prior to today, the authors conclude that	16	correct?
17	transvaginal permanent mesh kits such as Prolift	17	MR. KOOPMANN: Object to form; asked and
18	are associated with higher rates of reoperation for	18	answered.
19	prolapse, stress urinary incontinence or mesh	19	A. Yeah, that's correct.
20	exposure, and higher rates of bladder injury at	20	Q. (By Mr. Bentley) Do you agree with the
21	surgery and de novo urinary incontinence. Do you	21	authors of the 2016 Cochrane review that concluded
22	agree with that conclusion?	22	that permanent mesh implants such as Prolift are
23	A. I would have to separate all those	23	associated with a higher reoperation rate for
24	statements. There's a lot there to agree or	24	stress urinary incontinence? Do you agree with
25	disagree with.	25	that statement?
23	disagree with.		that statement:
	Page 219		Page 221
1	Q. Okay. Do you agree that permanent mesh	1	A. I don't agree with the statement.
2	kits for prolapse like Prolift are associated with	2	Q. And in your report, have you provided
3	higher rates of reoperation for prolapse?	3	any type of analysis or reason as to why you
4	A. No, I don't agree with that.	4	disagree with that statement?
5	Q. And in your report, you haven't given us	5	A. Yeah, I think I've stated to the
6	any reason to your methodology in reaching a	6	contrary, from my review of other medical
7	disagreement with the systematic review of Cochrane	7	literature.
8	that was published in 2016; isn't that correct?	8	Q. Right. But in your report, you haven't
9	A CONT of the control		
	A. That's not correct.	9	explained why you disagree with the 2016 Cochrane
10	A. That's not correct. Q. I'm sorry. Where in your report do you	9	explained why you disagree with the 2016 Cochrane review's conclusions that it's that mesh kits
10 11			
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11	Q. I'm sorry. Where in your report do you give us any type of analysis as to why you disagree	10 11	review's conclusions that it's that mesh kits such as Prolift are associated with a higher
11 12	Q. I'm sorry. Where in your report do you give us any type of analysis as to why you disagree with this 2016 Cochrane review's conclusions?	10 11 12	review's conclusions that it's that mesh kits such as Prolift are associated with a higher reoperation rate for stress urinary incontinence;
11 12 13	Q. I'm sorry. Where in your report do you give us any type of analysis as to why you disagree with this 2016 Cochrane review's conclusions? A. Because I think I cite other Cochrane	10 11 12 13	review's conclusions that it's that mesh kits such as Prolift are associated with a higher reoperation rate for stress urinary incontinence; isn't that correct?
11 12 13 14	Q. I'm sorry. Where in your report do you give us any type of analysis as to why you disagree with this 2016 Cochrane review's conclusions? A. Because I think I cite other Cochrane reviews from Maher as well as other systematic	10 11 12 13 14	review's conclusions that it's that mesh kits such as Prolift are associated with a higher reoperation rate for stress urinary incontinence; isn't that correct? MR. KOOPMANN: Object to form.
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11 12 13 14 15 16 17 18 19 20 21	Q. I'm sorry. Where in your report do you give us any type of analysis as to why you disagree with this 2016 Cochrane review's conclusions? A. Because I think I cite other Cochrane reviews from Maher as well as other systematic reviews suggesting that just the opposite, that the incidence of reoperation is lower with graft-augmented repair such as Prolift when compared to native tissue repair. MR. KOOPMANN: Object to the form of that last question. Q. (By Mr. Bentley) Do you have any knowledge or understanding as to what this 2016	10 11 12 13 14 15 16 17 18 19 20 21	review's conclusions that it's that mesh kits such as Prolift are associated with a higher reoperation rate for stress urinary incontinence; isn't that correct? MR. KOOPMANN: Object to form. A. That's correct. Q. (By Mr. Bentley) Doctor, do you agree with the 2016 Cochrane author's conclusion that permanent mesh is associated with higher rates of reoperation for mesh exposure? MR. KOOPMANN: Object to form. A. Compared to what? Q. (By Mr. Bentley) To nonpermanent mesh
11 12 13 14 15 16 17 18 19 20 21	Q. I'm sorry. Where in your report do you give us any type of analysis as to why you disagree with this 2016 Cochrane review's conclusions? A. Because I think I cite other Cochrane reviews from Maher as well as other systematic reviews suggesting that just the opposite, that the incidence of reoperation is lower with graft-augmented repair such as Prolift when compared to native tissue repair. MR. KOOPMANN: Object to the form of that last question. Q. (By Mr. Bentley) Do you have any	10 11 12 13 14 15 16 17 18 19 20 21	review's conclusions that it's that mesh kits such as Prolift are associated with a higher reoperation rate for stress urinary incontinence; isn't that correct? MR. KOOPMANN: Object to form. A. That's correct. Q. (By Mr. Bentley) Doctor, do you agree with the 2016 Cochrane author's conclusion that permanent mesh is associated with higher rates of reoperation for mesh exposure? MR. KOOPMANN: Object to form. A. Compared to what?

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1	2016 Cochrane review do you agree with their	1	They may have; they may not have.
2	conclusions that Prolift and permanent mesh kits	2	Q. Doctor, we previously discussed that you
3	are associated with a higher rate of bladder injury	3	hold a theory that mesh pain might be related to
4	at surgery and de novo stress urinary incontinence?	4	infection; is that correct?
5	A. When compared to native tissue repairs?	5	A. It's one of possible many theories, yes.
6	Q. Yes.	6	Q. And my previous questions were, where in
7	A. Yes.	7	your report do you discuss this theory that the
8	Q. And the authors of the 2016 Cochrane	8	pain that many of these patients are suffering
9	review also conclude that the risk-benefit profile	9	might be attributable to mesh-related infection?
10	means that transvaginal mesh has limited utility in	10	Do you discuss that anywhere in your report?
11	primary surgery. Do you agree with that statement?	11	A. No.
12	A. No, I do not.	12	Q. And that's not discussed in the IFU,
13	Q. But as you've previously testified,	13	right?
14	there's a narrower patient profile that you think	14	A. Infection's discussed in the IFU.
15	is appropriate for using Prolift or Prolift+M as a	15	Pain's discussed in the IFU.
16	primary surgery, right?	16	Q. But the theory that the pain is being
17	A. Yes.	17	caused by a mesh-related infection, that's not
18	Q. And I believe you testified that system	18	discussed, right?
19	reviews have a preset inclusion and exclusion	19	A. IFU's not going to discuss theories.
20	criteria for which studies or how they're going	20	Q. It's not discussed in the IFU, right?
21	to approach which studies to analyze; is that	21	A. It's not discussed.
22	correct?	22	Q. Doctor, you testified about the 2011
23	A. They should, yes.	23	Altman RCT earlier; do you remember that?
24	Q. And you don't have a preset inclusion	24	A. I do.
25	criteria for which studies you analyze in your	25	Q. And was that an important study to you?
	Page 223		Page 225
1	report; isn't that correct?	1	A. It was.
2	A. I have criteria. I mentioned those	2	Q. Do you know if there were systematic
3	criteria earlier.	3	problems with the POPQ measurements in that study?
4	Q. And what were the criteria strike	4	A. I'd have to take a look at the study
5	that.	5	again if you want to go through that. I would be
6	And do you have a preset exclusion criteria	6	surprised to hear that.
7	for which studies you didn't discuss in your	7	Q. As you sit here today, you don't have
8	report?	8	any knowledge regarding that, though?
9	A. I have an inclusion criteria, I guess	9	A. No.
10	you can flip that and make it exclusion, but as I	10	Q. Do you know who Dr. Jeffrey Drazen is?
	mentioned earlier, I look for studies that are	11	A. No, I do not.
11 12		12	Q. I'll represent to you that Dr. Drazen
13	well-designed of high levels of evidence, that are	13	
	from reputable peer-reviewed journals, that have a		was the editor in chief of the New England Journal
14	large cohort of patients, preferably multi-center	14	of Medicine and that he was deposed in the Ethicon
15	studies, et cetera.	15	litigation. Do you know if you've reviewed his
16	Q. And did we discuss a couple of studies	16	deposition testimony?
17	that you felt were reputable and important studies	17	A. No, I have not.
18	that could have met your inclusion criteria?	18	Q. So if I told you that he testified that
19	MR. KOOPMANN: Object to form.	19	there were issues with the POPQ measurements, you
20	A. We discussed studies that I didn't	20	would have no information one way or the other if
21	include in my report, yes.	21	that was correct or not?
22	Q. (By Mr. Bentley) Would they have met	22	MR. KOOPMANN: Object to form; foundation.
23	your inclusion criteria?	23	A. As I mentioned earlier, I'd be surprised
24	A. I would have to look at them more	24	to hear that experienced surgeons would have
25	specifically. I didn't have time to look at those.	25	problems measuring taking POPQ measurements.

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	Page 226		Page 228
1	Q. (By Mr. Bentley) Would it affect your	1	Q. (By Mr. Bentley) And the initial IFU,
2	opinions on your evaluation of the reliableness of	2	you don't know how this could be included; is that
3	the Altman study if you learned that there were,	3	your testimony?
4	indeed, problems with the measurements of the POPQ?	4	A. That's my testimony, yes.
5	MR. KOOPMANN: Object to form.	5	Q. But once the Prolift came to market and
6	A. Was he a reviewer of that article, or	6	the information that's provided in this monograph
7	did he write a published editorial on that article?	7	was obtained, do you know of any reason why Ethicon
8	Q. (By Mr. Bentley) I'm going to re-ask my	8	couldn't have provided that information in an
9	question, Doctor.	9	updated IFU?
10	If Dr. Drazen testified that there were,	10	A. I think they did a good job providing
11	indeed, problems with the POPQ measurements in the	11	the information in the form of the Prolift
12	Altman 2011 study, assuming that, would that affect	12	monograph. That's more than what you would see
13	your evaluation of whether or not that study was	13	with any other product like Elevate or Bard
14	reliable?	14	Avaulta. I've never seen anything like this
15	A. No, it would not.	15	monograph for any other mesh kit on the market,
16	Q. You don't care if there were problems	16	whether it's for prolapse or incontinence.
17	with the POPQ measurement in the study you relied	17	MR. BENTLEY: I'm going to strike as
18	upon?	18	nonresponsive.
19	A. The fact that Dr. Drazen has that	19	Q. (By Mr. Bentley) Doctor, my question
20	opinion in his deposition doesn't make that	20	is, is there any legal reason why Ethicon could not
21	statement true. That's his opinion. I don't	21	have updated the Prolift IFU with the technical
22	believe that's the opinion of Dr. Altman and his	22	pearls that are detailed in the Surgeon's Resource
23	coauthors, that they had problems measuring POPQ.	23	Monograph?
24	Q. And Doctor, you testified earlier about	24	MR. KOOPMANN: Object to form; asked and
25	the Prolift Surgeon's Resource Monograph; do you	25	answered.
	Page 227		Page 229
1	remember that?	1	A. I'm not aware of any legal reasons, but
2	A. I do.	2	I think there's a lot of practical reasons why it
3	Q. And I believe you testified that the	3	would not have been in an IFU.
4	monograph contains some technical pearls; is that	4	MR. BENTLEY: I'm going to strike after
5	correct?	5	"legal reasons."
6	A. Technical pearls, that's correct.	6	Q. (By Mr. Bentley) Doctor, do you have
7	Q. And what's the purpose of providing	7	any understanding as to whether every surgeon that
8	technical pearls to surgeons?	8	implanted the Prolift received the monograph that
9	A. Technical pearls are to help newer	9	you reviewed?
10	surgeons gain insight that's only relevant after	10	A. I don't have a way of knowing that, no.
11	doing a certain number of cases. So it's a way of	11	Q. Is the monograph included with every
12	more experienced surgeons sharing information with	12	Prolift or Prolift+M product as it's sold?
13	others.	13	A. I don't know the answer to that.
14	Q. And you believe that's helpful, right?	14	Q. But the IFU you know is provided with
15	A. Yes, it's helpful.	15	the Prolift or Prolift+M with every product sold,
16	Q. Do you have any legal basis for why	16	right?
17	Ethicon couldn't have included that information in	17	A. The IFU, yes.
18	the IFU procedural steps?	18	MR. BENTLEY: I have no further questions.
19	MR. KOOPMANN: Object to form.	19	Thank you.
20	A. This is a 25-page document that was	20	MR. KOOPMANN: Just a couple follow-ups,
21	collected years after Prolift was launched, and	21	Dr. Flynn.
22	it's just a wealth of information on the	22	EXAMINATION
23	experience. So there's no way this could have been	23	BY MR. KOOPMANN:
24	included in the IFU at its onset. So I don't know	24	Q. Do you think there's a surgeon in
	included in the free at its offset. But don't know		
25	how this could have been included in the IFU.	25	America who is unaware that an infection can cause

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	Page 230		Page 232
1	pain?	1	
2	MR. BENTLEY: Objection; speculation, form	2	
3	and foundation, asked and answered.	3	
4	A. No.	4	
5	Q. (By Mr. Koopmann) If somebody cuts	5	I, BRIAN FLYNN, M.D., do hereby certify that
6	their finger and that cut, that little cut on their	6	I have read the foregoing transcript and that the
7	finger gets infected, will that cause pain?	7	same and accompanying amendment sheets, if any,
8	MR. BENTLEY: Objection; argumentative.	8	constitute a true and complete record of my
9	A. Yes.	9	testimony.
10	MR. BENTLEY: Form.	10	
11	Q. (By Mr. Koopmann) Did you ever hear of	11	
12	the Altman 2011 RCT being retracted by the New	12	
13	England Journal of Medicine?	13	Signature of Demonstra
14	A. No.	14	Signature of Deponent
15	Q. Is that something that happens from time	12	() No Amendments
16	to time with an article if there's some significant	16	() Amendments Attached
17	problem with an article?	17	Subscribed and sworn to before me
18	MR. BENTLEY: Objection; form and	18	this day of, 2016
19	foundation, speculation, vague.	19	
20	A. Yes, it does happen. I've seen articles	20	Notary Public:
21	be retracted from the literature when new	21	Address:
22	information's been discovered.	22	
23	MR. KOOPMANN: No further questions.	23	My commission expires:
24	(Discussion held off the record.)	24	Seal:
25	EXAMINATION	25	
	Page 231		Page 233
1	BY MR. BENTLEY:	1	
2	Q. Doctor, I'm handing you what's titled	2	
3	"Expert Report Re: Gynecare Prolift Pelvic Floor	3	MLG
4	Repair System." It's a report dated February 26,	4	
5	2016, and it appears to have your signature on this	5	
6	last page. Does that look like your report entered	6	REPORTER'S CERTIFICATE
7	in this litigation?	7	STATE OF COLORADO)
8	A. Yes, it does.) ss.
9	Q. And I'm handing you a similar report	8	COUNTY OF DENVER)
10	titled "Prolift+M." Does that look like your	9	
11	report regarding the Prolift+M products in this	10	I, MELANIE L. GIAMARCO, do hereby certify that I an
12	litigation?	11	a Registered Professional Reporter and Notary Public within
13	A. It does.	12	the State of Colorado; that previous to the commencement of
14	MR. BENTLEY: Thank you.	13	the examination, the deponent was duly sworn by me.
15	MR. KOOPMANN: Are you going to mark those	14	I further certify that this deposition was taken in
16	as exhibits?	15 16	machine shorthand by me at the time and place herein set forth, that it was thereafter reduced to typewritten form, and
17	MR. BENTLEY: Please mark those as 11 and	17	that the foregoing constitutes a true and correct transcript
18	12. Prolift will be 11, +M will be 12.	18	of the proceedings had.
19	(Exhibits 11 and 12 were marked for	19	I further certify that I am not employed by, related
20	identification.)	20	to, nor of counsel for any of the parties herein, nor
21	(Whereupon, the deposition was concluded at	21	otherwise interested in the result of the within litigation.
	5:50 p.m. on April 14, 2016.)	22	In witness whereof, I have affixed my signature and
22	1 ,	1	
22 23	r , , , , ,	23	seal this 18th day of April, 2016.
	, , , , , , ,	23 24	seal this 18th day of April, 2016.

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1	Melanie L. Giamarco	
2	Registered Professional Reporter	
3	Registered Merit Reporter	
4	Certified Realtime Reporter	
5	My commission expires: Avayet 25, 2017	
	My commission expires: August 25, 2017.	
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